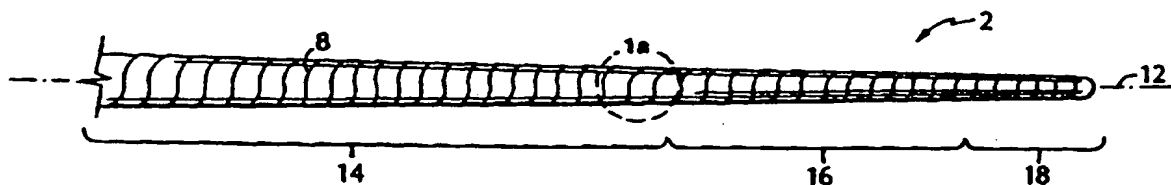


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 5/00		A1	(11) International Publication Number: WO 96/26671
		(43) International Publication Date: 6 September 1996 (06.09.96)	
(21) International Application Number: PCT/US96/02265		HARTNETT, John, F. [US/US]; 27 Beechwood Road, Wellesley, MA 02181 (US). REID, Robert, B. [US/US]; 16 Woodcrest, Westborough, MA 01581 (US). ROWLAND, Christopher, A. [US/US]; 171 Stearns Road, Marlborough, MA 01752 (US). WARICH, Charles [US/US]; 5 Genesee Circle, Milford, MA 01757 (US). SVATEK, Thomas, A. [US/US]; 581 Cross Street, Carlyle, MA 01741 (US). (74) Agent: GAGEL, John, J.; Fish & Richardson P.C., 225 Franklin Street, Boston, MA 02110 (US). (81) Designated States: CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.	
(22) International Filing Date: 28 February 1996 (28.02.96)			
(30) Priority Data: 08/395,923 28 February 1995 (28.02.95) US			
(60) Parent Application or Grant (63) Related by Continuation US 08/395,923 (CIP) Filed on 28 February 1995 (28.02.95)			
(71) Applicant (for all designated States except US): BOSTON SCIENTIFIC CORPORATION [US/US]; One Boston Scientific Place, Natick, MA 01760-1537 (US).			
(72) Inventors; and (75) Inventors/Applicants (for US only): WANG, James, C. [US/US]; 15 Massasoit Avenue, Norton, MA 02766 (US). CHIN, Albert [US/US]; 25 Bernard Street, Newton, MA 02161 (US). DAIGLE, James, B. [US/US]; 3745 Ridge View Court, Morgan Hill, CA 95037-6820 (US). DANIELS, Douglas, J. [US/US]; 15 Pudding Stone Lane, Mendon, MA 01756 (US). DEMELLO, Richard, M. [US/US]; 108 River Street, Acton, MA 01720 (US).			

(54) Title: POLYMERIC IMPLEMENTS FOR TORQUE TRANSMISSION



(57) Abstract

Implements, particularly medical instruments, formed at least in part of elongated polymer members, exhibit high torque fidelity after processing with tension, heat, and twisting. The processing orients the polymer in generally helical paths so that torque imposed at the proximal end can be transmitted to the distal end without substantial whipping, even if the implement follows a long and tortuous pathway. Applications include a medical guide wire (2) with stiff portion (14), transition portion (16) and flexible portion (18), a catheter (140) and a sphincter (170).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LJ	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

POLYMERIC IMPLEMENTS FOR TORQUE TRANSMISSION

Field of the Invention

This invention relates to polymeric implements
5 that transmit torque.

Background of the Invention

Torque transmission is important in many areas.
For example, in the field of less invasive surgery,
catheters and guidewires are threaded along tortuous
10 paths to treatment sites deep within the body by
torquing and pushing their proximal end. Positioning
these devices is easier if they have torque transmission
characteristics such that when the physician rotates the
proximal end, the distal end rotates by a corresponding
15 amount. Accurate torque transmission is also important
for medical devices with rotating parts, such as an
acoustic imaging catheter with a transducer that is
rotated by a driveshaft.

Summary of the Invention

20 In an aspect, the invention features an elongated
medical instrument formed at least in part by an extended
element that is subject to torque in use. The element is
a structural body composed of polymer that is helically
oriented about the instrument axis.

25 In another aspect, the invention features an
elongated medical instrument formed at least in part of
an extended element that is a structural body composed of
polymer. The element has a length between about 40 to
300 inch and an outer diameter of about 0.25 inch or
30 less. The element is capable of substantially 1:1 torque
transmission between the proximal and distal ends without
substantial whipping when the member is looped in a
circle with a diameter about 5 inch at a point about half
way along its length.

- 2 -

In another aspect, the invention features an elongated medical instrument formed at least in part of an extended element and a method for forming the element. The element is a structural body that is composed of
5 polymer and which is the product of the process of providing an elongated polymer member, heating the polymer member above its glass transition temperature but below its melting temperature, simultaneously twisting and tensioning member, and cooling the member to set the
10 effect of the twisting and tensioning into the member.

Embodiments may include one or more of the following. The element may have a length of about 40 inch or more and a diameter of about 0.25 to 0.008 inch. The helical paths may have a pitch length that is about
15 1.5 or more times the outer diameter of the element. The helical paths may have a pitch length from about 2 to about 5 times the outer diameter of the element.

Embodiments may also include one or more of the following. The medical instrument may be composed
20 entirely of polymer. The polymer may be a semi-crystalline polymer. The polymer may be PET, Nylon, or PEBAX. The polymer may be oriented or heat set at a temperature substantially greater than sterilization temperature.

25 Embodiments may also include one or more of the following. The element may be in the form of a solid polymer rod. The element may be in the form of a tube. The medical instrument may be in the form of a composite of an elongated metal member and the polymeric element.
30 The element may be a coextrusion of polymers. The element may be a coextrusion of different polymers. The instrument may have differential stiffness along its axis. The element may include polymer molecules oriented on helical paths and polymer molecules oriented linearly,
35 along the axis. The element may include polymer

- 3 -

molecules oriented on helical paths oriented about the axis in opposite directions. The element may include a first polymer layer with polymer molecules oriented along helical paths extending in one direction about the axis
5 and a second polymer layer with polymer molecules oriented along helical paths extending in the opposite direction about the axis. The medical instrument may be in the form of a medical guidewire. The medical instrument may be in the form of a medical catheter
10 having a lumen therethrough. The medical instrument of may be stiffer in a proximal portion than a distal portion.

Embodiments may also include one or more of the following. The process may include stretching the member
15 by the tensioning. The process may include placing the polymer member in tension and rotating one end of the polymer member while holding the other end rotationally stationary. The process may include simultaneously heating, twisting, and stretching. The process may
20 include providing a member having differential stiffness along its length. The process may include heating to improve dimensional stability. The process may include forming a tube by providing an elongated polymer member constructed of a jacket and core composed of different
25 polymers, heating, twisting, tensioning, and cooling the member, heating to a temperature sufficient to melt or relax the core polymer without melting or relaxing the core polymer, and removing the core polymer to form a lumen.

30 In another aspect, the invention features an apparatus for manufacturing an elongated element that is subject to torque in use and composed of polymer. The apparatus includes first and second holding stations spaced along a linear path and constructed to grip a
35 preformed polymer member. Translating apparatus is

- 4 -

provided for moving the first and second stations along the path to place the preformed polymer member in tension. Torquing device is provided for imposing torque on the preformed member, and

- 5 a heater is located between the first and second stations for heating a portion of the preformed member.

Embodiments may include one or more of the following. The torquing device may be a rotatable chuck provided at the first holding station. The translating
10 apparatus may be constructed to move the stations along the linear path in the same direction. The translating apparatus may be constructed to move the second station faster than the first station to stretch the member therebetween. The second holding station may include a
15 series of grippers to hold and support a processed length of the member while other portions are processed. The heater may heat the member without contacting the member. The heater may be a heat gun. The translating apparatus may be constructed to vary the translation speed of the
20 stations during the course of a processing. The torquing device may be constructed to vary the torque during the course of processing the member. The translating apparatus, torque device, and heater may be constructed to reverse the direction of movement along the path while
25 keeping the member in tension and without torquing, to heat the member to improve dimensional stability. The holding stations and torque device may be constructed to contact the member on its exterior surface. The holding stations and torque device may be constructed to contact
30 a preformed polymer tubular member with a core member extending therethrough in a manner to permit torquing and tensioning the polymer member without torquing or tensioning the core member, while translating the tubular member and core member along the path. The torquing
35 element may be a rotatable chuck positioned at the first

- 5 -

station permitting gripping and torquing the polymer member without gripping or torquing the core and the second station includes a gripping element that grips the polymer member and the core together.

5 In another aspect, the invention features an elongated medical instrument that is delivered into tortuous pathways deep within the body. The instrument has an extended element having differential stiffness along its length, composed of homogenous structural
10 polymer that is helically oriented about the instrument axis.

Embodiments may also include one or more of the following. The element may include polymers of differing stiffness along its length. The element may include
15 variable diameter along its length. The element may be stiffer in proximal portions than distal positions. The instrument may be a tube-form catheter. The instrument may be a solid rod-form. The instrument may be a guidewire.

20 In another aspect, the invention features an elongated implement that is torqued in use. The implement has an extended element having a first portion composed of a polymer that is helically oriented about the instrument axis and a second portion composed of polymer
25 in a different orientation.

Embodiments may also include one or more of the following. The second portion may be composed of polymer that is helically oriented in the rotational direction opposite the helical orientation of the first portion.
30 The second portion may be composed of polymer that is linearly oriented. The first and second portions may be separate layers. The first and second portions may be disposed along the length of the device. The implement may be in the form of a tube. The implement may be in the

- 6 -

form of a solid rod-form. The implement may be in the form of a rotatable drive shaft.

In another aspect, the invention features an elongated implement that is subject to torque in use.

- 5 The implement includes an extended jacket element composed of polymer that is helically oriented about the implement axis and positioned over a core element.

Embodiments may also include one or more of the following. The core element may be a metal wire. The
10 wire may be a superelastic material. The core may be a glass filament.

In another aspect, the invention features an elongate implement that is subject to torque in use. The implement has a first portion made of an extended jacket
15 element of polymer positioned over a core element, and a second portion composed substantially of a polymer.

Embodiments may include one or more of the following. The core element extends partially into the second portion. The first portion has substantially
20 greater length than the second portion. The second portion is substantially of a polymer that is helically oriented about the instrument axis.

In another aspect the invention features a medical procedure on a body. The procedure includes providing an
25 elongated medical instrument formed at least in part by an extended element that is subject to torque in use. The element is a structural body of polymer that is helically oriented about the instrument axis. The procedure also includes delivering the medical instrument
30 into the body and applying torque to the part comprised of polymer that is helically oriented about the instrument.

Embodiments may also include one or more of the following. The procedure includes providing the medical
35 instrument in the form of a guidewire and delivering the

- 7 -

instrument into a body lumen by urging and torquing an end of the instrument. The procedure includes applying electrical or magnetic energy in proximity to the medical instrument. The procedure is a sphincterotome procedure and the part made of polymer is made entirely of polymer near the distal end of the guidewire. The procedure includes delivering the guidewire into a body lumen, guiding a sphinctertome into the lumen over the guidewire, the sphinctertome including an electrically-energized resecting element near its distal end adapted to resect tissue, and resecting tissue with the resecting element while maintaining the guidewire in axial location corresponding to the resecting element.

Embodiments also include one or more of the following. The medical procedure is performed while simultaneously conducting magnetic resonance imaging of the body. The procedure is a less invasive procedure. The procedure includes delivering a guidewire into the body. The procedure includes delivering a catheter into the body. The procedure includes delivering the medical instrument into the body through an entry needle formed of metal.

Embodiments may also include one or more of the following advantages. For example, whipping can be decreased or eliminated in guidewires, catheters, and other devices. Whipping can occur if torque is not efficiently transmitted, causing a device to become twisted and wound along its length. If the distal end of the member does not respond to the rotational torque applied at the proximal end in a one-to-one relationship, then the torsional energy is stored in the length of the member and the distal tip will whip when a threshold energy is reached.

In embodiments, rotational fidelity between the proximal and distal ends may be substantially 1:1, even

- 8 -

for devices of extended length, e.g., 20 inch or more, e.g. 75 inch, that follow a tortuous path, e.g., a tight circle.

Moreover, by providing high torque fidelity components according to the invention, the use of common polymers in medical devices can be extended. Accordingly, the invention can reduce instrument weight, improve device lubricity, simplify manufacture, and lower cost.

Further features, aspects, and advantages follow. For example, in some further aspects, the invention features methods of medical treatment using polymeric torque transmission elements and apparatus for forming polymeric torque transmitting elements, as well as non-medical devices and methods employing torque transmission.

Description of the Preferred Embodiments

We first briefly describe the drawings.

Drawings

Fig. 1 is a side view of a polymer medical guidewire, while Fig. 1a is a greatly expanded view of a small portion of a segment of the guidewire that has been oriented to follow a characteristic helical path, and Fig. 1b is a greatly expanded schematic of oriented polymer molecules within the segment;

Fig. 2 is a schematic of the guidewire in Fig. 1 being delivered into a patient, while Figs. 2a and 2b are greatly expanded views illustrating torquing of the proximal end and rotation of the distal end, and Fig. 2c is a view of an angioplasty catheter being threaded over the guidewire;

Fig. 3 is a top view schematic of an apparatus for manufacture of high torque fidelity instruments, while Fig. 3a is an illustration of a torque transmission test;

Fig. 4 is a cross-sectional side view of a guidewire as described in Example 1, while Fig. 4a is a cross-sectional side view of a member which can be processed to form the guidewire;

5 Fig. 5 is a cross-sectional side view of a guidewire according to the invention as described in Example 2, while Fig. 5a is a similar view of a polymer member which is processed to form the guidewire;

10 Fig. 6 is a cross-sectional side view of a guidewire as discussed in Example 3;

Figs. 7 and 7a are schematics illustrating manufacture of the guidewire in Fig. 6;

Fig. 8 is a cross-sectional side view of a guidewire as described in Example 4;

15 Figs. 9 to 9b are schematics illustrating the manufacture of the guidewire in Fig. 8;

Fig. 10 is a cross-sectional side view of a guidewire as described in Example 5;

20 Fig. 11 is a cross-sectional side view of a catheter as described in Example 6, while Fig. 11a is a similar view of a polymer member which is processed to form the catheter;

25 Fig. 12 is a cross-sectional side view of a catheter as described in Example 7, while Fig. 12a is a cross-sectional side view of a polymer member which can be processed to form the catheter.

Fig. 13 is a cross-sectional sideview of a guidewire described in Example 8, while Fig. 13A is a view of the wire in use with a sphinctertome.

30 Structure

Referring to Fig. 1, a guidewire 2 includes a relatively stiff proximal portion 14, a transition portion 16 with varying, intermediate stiffness, and a highly flexible distal portion 18. The guidewire is

- 10 -

formed entirely of common medical polymer materials and exhibits high torque fidelity because it has been twisted and tensioned in manufacture to helically orient the polymer. This is illustrated by a segment 8 of the wire that, prior to processing, was parallel to the device axis but after twisting and tensioning, follows a characteristic helical path.

Referring as well to Fig. 1a, a greatly enlarged view of a portion of segment 8, the helical orientation can be characterized by a pitch length PL, which is the length that the characteristic helical path extends along the axis for each 360° rotation about the axis. The pitch length is a measure of how tightly the helical orientation is wrapped about the axis. As discussed below, the pitch length can be determined by drawing a line parallel to the axis of a preformed polymer member prior to processing. After processing, the line traces a characteristic helical path which can be measured.

Referring as well to Fig. 1b, a greatly enlarged, molecular level schematic of a portion of the segment 8, it is believed that the molecules of the polymer are oriented along helical paths as a result of twisting and tensioning. This orientation improves the transmission of torque along the length of the guidewire, which can make it easier to deliver through a tortuous body lumen. The process of twisting the polymer, as will be discussed in detail below, reduces asymmetries in the polymer, which reduces or eliminates whipping.

Referring to Fig. 2, in the course of an angioplasty operation to open an occluded coronary artery, the guidewire 2 is typically delivered through an access catheter 20 into the femoral artery 22. The physician pushes and torques the proximal end of the guidewire to thread it through the body into the coronary arteries 24.

- 11 -

Referring as well to Figs. 2a and 2b, the distal portion 18 of the guidewire is positioned such that it can cross a restricted region 28 of the artery. The physician pushes (arrow 30) and torques (arrows 32, 33) the proximal portion of the guidewire remaining outside the body. The degree of rotation caused by torquing the proximal end is transmitted to smoothly produce an equal degree of rotation at the distal end. For example, as indicated by marker lines 19, 19' if the physician rotates the proximal end θ , e.g. 60° , the distal end smoothly rotates θ , 60° in the same direction without substantial whipping.

Referring to Fig. 2c, once the guidewire is positioned across the occlusion, a catheter, such as an angioplasty balloon catheter 35 is threaded over the guidewire. The body of the catheter is also formed by twisting to improve its torque transmission to facilitate delivery. The catheter is torqued and pushed from the proximal end to position the balloon 37 adjacent to the occluded area 28. After positioning, the balloon is inflated to expand the restricted area, then deflated, and the catheter and guidewire are removed by torquing and pulling from the proximal end. The guidewire is removed in a similar manner.

25 Manufacture

Referring to Fig. 3, high torque fidelity devices can be manufactured with a system 40 that permits placing a preformed polymer member 60 in tension, heating the member, stretching the member, twisting the member, and cooling the member. To place the member in tension, the system 40 includes first and second holding stations 42, 44, both of which can be translated along tracks 45, 47 (e.g., 6 foot translation distance) by rotating-screw translators 46, 48 that are driven by motors 50, 52. To

- 12 -

twist the member, one end, the proximal end, of polymer member 60 is held at station 42 by a rotatable chuck 59. The chuck is connected to a motor 58 to torque (arrow 56) the member about its axis. The other end of the member
5 is held at station 44 by compression fittings 63, 67, e.g., Touhy-Borst type fittings that do not permit rotation. Fitting 63 and fitting 65 can be positioned at various distances along on arm 43 and set, e.g., with a set screw. The multiple fittings reduce the tension on
10 the distal portion of the member, which is typically thin and soft, while more proximal portions are processed. To heat the member along a short length (e.g., about 1 cm), a heater stage 54 (475 watt heat gun) is provided between the holding stations. Temperature is estimated by
15 measuring the output air of the heat gun with a thermocouple. An infrared heater can also be used.

To improve the torque fidelity of the member 60, the stations 42 and 44 are moved in the same direction but station 44 moves at a higher rate than station 42
20 (arrows 62, 64), putting the polymer member in tension and causing it to be translated past the heater (arrow 69). At the same time, the end of the member held at station 42 is rotated (arrow 56). The heater 54 directly heats a short section of the member to soften it and
25 permit the member to be stretched due to the tension, while being twisted due to the rotation at station 42. The portions of the polymer that are translated beyond the heater cool and harden, setting the effects of rotation and tension into the polymer.

30 Referring to Fig. 3, a segment of the preformed member running parallel to the longitudinal axis of the member prior to processing, as indicated by line portion 61, is helically deformed during processing, as indicated by line portion 61'. The process increases the modulus
35 of the member in the transverse direction. The process

- 13 -

also reduces asymmetries (e.g., ridges, troughs, oval, and bends) in the polymer member.

The preformed polymer member may be, for example, in the form of a rod, a tube, polymer-metal composite, or
5 polymer/non-metal composite. Prior to processing, the polymer may have any molecular orientation. For example, the polymer may be completely unoriented or it may be oriented, for example, linearly. The member may be preformed by extrusion, molding or other techniques. The
10 member may be coextruded with multiple polymer layers. The coextrusion may have different polymers along its length that give the member and the finished device variable stiffness. Suitable coextrusion techniques are described in Wang U.S.S.N. 08/230,333, and 08/230,310,
15 both filed April 20, 1994, their entire contents being incorporated herein by reference. The length and diameter of the preformed polymer member are selected based on the desired length and diameter of the desired oriented device, accounting for the process draw ratio.
20 The length of the member should include some excess to allow for the portion of the member gripped at the holding stations and the length of the heating area. This excess, which is not oriented, is trimmed after processing. For example, in a typical case,
25 approximately 2" is trimmed from the distal end and approximately 10" (mostly not oriented) is trimmed from the proximal end. (Trimming lengths depends on system configuration and dimension and on how far the orientation is allowed to go beyond the needed length.)
30 The polymer may be a conventional, homogenous, biocompatible structural polymers, such as engineering thermoplastics, with mechanical characteristics, such as flexibility and softness, that are selected based on the desired device performance. For example, the polymer may
35 be a semi-crystalline polymer such as PET or nylon. Non-

- 14 -

crystalline or amorphous polymers, such as polyurethanes, may also be worked as described above to improve torque transmission. Since these latter polymer types generally are not heat set, they are used in applications where the temperature is well below the softening or melting temperature, above which the effect of twisting might be relaxed. For most applications, the polymer should be capable of maintaining good torque transmission after being heated to temperatures commonly used for sterilization, such as about 70° C (e.g., for ethylene oxide sterilization). The polymers that can be used include, for example, polyamides, including nylon 6, nylon 66, nylon 11, nylon 12, Pebax nylons (polyether block amide copolymers, e.g. PEBAX 3533, 5533, 6333, 7033, 6033, 5033), and polyamide elastomers, polyesters including PET (polyethylene terephthalate), PBT (polybutylene terephthalate), PEN, PMMA (polymethyl methacrylate (acrylic)) and polyester elastomers, polyolefins such as polyethylene, polypropylene and polyolefin copolymers and elastomers, polystyrene and its copolymers, including ABS and SAN, polyurethanes including stiff and elastomeric formulations, PVC (polyvinyl chloride) and its copolymers, PVDC (polyvinyl dichloride (Kynar)) EVOH and its copolymers, polycarbonates, and various blends and polymer alloys.

Irradiated polymers can be used as the shaft stock. In this case, a tubing or rod is made from a plastic such as HDPE (high density polyethylene), PVC or other irradiatable polymer is exposed to high-energy electrons in a commercial e-beam vault. The high-energy electrons induce the macromolecules to crosslink and form a three-dimensional network. The crosslinking occurs in the amorphorous regions in semi-crystalline materials such as HDPE. When heated above the original melt temperature and subjected to helical strains in the

processing steps, the crystalline regions (which are not crosslinked) will melt while the crosslinked amorphorous regions will deform similar to a natural rubber. When cooled, the crystalline regions reform and "freeze" the amorphorous, crosslinked regions under strain. The application temperatures for an element made with irradiated polymers should not exceed the temperatures used in the helical/longitudinal orientation process to avoid shrinkage of the shafts.

- 10 Longer polymer chain lengths may be preferable because, it is believed, they add strength to the device. For devices that will be flexed in use, fibrillation-resistant polymers should be used. Specific polymers can be chosen based on their Young's modulus, durometer, tensile strength, tensile elongation, and flexural modulus to produce desired flexibility, stiffness, and softness. For engineering thermoplastics, tensile strength is, for example, about 2000-12,000,000 psi, tensile elongation is about 2-1500%, e.g., 50-1000%, and flexural modulus is about 2-500,000 psi.

The properties of some engineering thermoplastics are given in the table below (see Modern Plastics Mid-October Encyclopedia Issue 1990):

- 16 -

MATERIAL	TENSILE STRENGTH (PSI X 1000) (ASTM D638)	TENSILE ELONGATION (%) (ASTM D638)	FLEXURAL MODULUS (psi x 1000) (ASTM D790)
PMMA	7-10,000	2.0-10	325-460
Nylon-6*	6,500	65	250
Nylon-6/6*	7,000	125	240
5 Nylon-11*	8,000	300	150
Nylon-12*	5-9,000	250-350	27-190
PEBAX Type*	2-7,000	350-680	3.0-65
Polycarbonate	9,500	110	345
PBT	8,200	50-300	330-400
10 PET	7-10,500	30-300	350-450
HDPE*	3-4,500	10-1200	145-225
Polypropylene	4-6,000	100-600	170-250
Polystyrene	5-7,500	1.2-2.5	380-490
PVDC*	3-5,000	160-240	55-95

15 * = Can be crosslinked via irradiation (e-Beam or gamma)

The polymers may be compounded with radiopaque particles, such as bismuth subcarbonate (e.g., 30% by weight) or tungsten (e.g., 80% by weight), prior to processing. The polymer may include reinforcing elements, such as metal wires or Kevlar fibers, that are oriented along with the polymer. However, a particular advantage of implements and methods described herein is that reinforcing elements are not necessary for imparting good torque transmission properties for most applications because of the orientation of the structural polymer.

For helical orientation, the polymer is typically heated to temperatures above the glass transition temperature but well below the melting point. For example, temperatures may be in the range of about 200-250°F. In embodiments, multiple heat treatments can be used. For example, the polymer may be oriented in a first heat treatment at a relatively low temperature of around 200°F, as described above. In a second, subsequent heat

treatment at a higher temperature, for example, about 300°F, the oriented polymer member is heated under tension but without rotation or stretching to heat set the polymer to improve its dimensional stability. This
5 can be achieved by running the oriented member back over the heater without rotation and only slight tension to prevent shrinking. Alternatively, heat setting can be performed in a separate oven equipped with a holders to maintain tension. Helical orientation and heat set may
10 be effected in a single operation for many polymers at a temperature of around 250°F. The temperature can be programmed to vary during the course of processing. This feature may be useful when forming a device that has different polymers along its length.

15 The rotation and translation speeds can be varied to affect the torque fidelity. This varies the pitch length of the helical paths. In embodiments, the pitch length, PL, is at least about 1.5, e.g., two to five times, the outer diameter of the oriented rod or tube.
20 The pitch length can be approximated by drawing a line (e.g., with permanent ink) parallel to the axis of the polymer member prior to processing. After processing, the line traces a helical pattern that approximates the helical orientation of the polymer. Typical rotation
25 rates are in the range of about 100-200 rpm. The ratio of the translation speed of the two stations is typically 2:1 to 4:1. The translation speed of each station is typically in the range of 10-100 cm/min. Very slow translation speeds are also possible. If the translation
30 speed is excessive, the polymer will not be heated sufficiently to cause twisting and stretching. In a case with a 3:1 stretch ratio, station 42 may be translated at about 30 cm/min, while station 44 is translated at about 90 cm/min, with the stations moving apart at about
35 cm/min. Larger diameter members can be processed at

- 18 -

slower speeds to permit sufficient heating time or a longer heating stage can be used. For larger members, active cooling apparatus can be used to quickly cool and quench the polymer.

5 The translation speeds can be programmed to vary stretch ratios and residence time over the heater. This feature may be particularly useful for manufacture of a device that has different polymers along its length or different orientation properties (e.g., pitch length)
10 along its length. The translation speed can also be varied to vary the stretch ratio and thus, the diameter of the finished device. Higher stretch ratios result in smaller diameters and, typically, lower device elongation. Translation speed should be sufficient to
15 allow the member to be heated above the glass transition temperature. The apparatus can be scaled to process many members simultaneously by providing multiple chucks and compression fittings at the holding stations and a heater of appropriate size. It is also possible to sequentially
20 treat the member by stretching under tension while heating but without twisting in a first step, followed by twisting while heating and placing the member under tension but without stretching in a subsequent step.

 After treatment, the member should be
25 substantially straight without excessive bends or a gross helical shape. In some cases, the torque transmission of the processed element can be improved by permitting the element to relax in an unrestrained state for a period of time (e.g., 4 to 24 hours) after processing. For
30 example, the member can be hung vertically from one end. During the relaxation period, the member may unwind several turns. Processed elements that have a pitch length in the preferred ranges and have been heat set are typically not relaxed prior to use. In addition, the
35 oriented devices should typically be stored or packaged

- 19 -

in a generally straight configuration rather than coiled. Likewise, the devices are kept straight during sterilization or any other heating process. In cases in which an element has been coiled in storage, it can be
5 straightened with a wire straightener device prior to use.

Referring to Fig. 3a, torque transmission can be tested by wrapping a processed, oriented element 3 near its mid-portion, at a location, L, e.g., about 40 inch
10 from the proximal end, around a rod 5 that has a diameter of about 5 inch. The proximal end is then rotated (arrow 7) and the distal end monitored to determine the amount of rotation and to monitor whipping. Under these conditions, polymer elements treated as discussed herein
15 can exhibit 1:1 torque transmission without substantial whipping. However, this test represents an extreme condition for many applications. Torque transmission can be improved by the techniques discussed above to levels sufficient for particular uses without achieving 1:1
20 transmission in this test.

The inventions will be further described by way of the following embodiment examples.

Example 1

Referring to Fig. 4, in an embodiment, a high
25 torque fidelity, variable stiffness guidewire 70 is formed entirely of a single polymeric material, PET. The guidewire has been helically oriented as indicated by segment line 75. The guidewire 70 has an overall length L_1 , about 60 inch. It includes a proximal portion 71
30 with a length L_2 , of about 54 inch and a diameter d_1 , about 0.035 inch, a tapering transition portion 72 with a length L_3 , about 3 inch, and a highly flexible distal portion 73 with a length L_4 , about 3 inch, and a diameter d_2 , about 0.005 inch. The guidewire terminates in an
35 atraumatic ball 77 that prevents vessel puncture.

- 20 -

Referring to Fig. 4a, the wire 70 can be formed from a polymer member 70' having an overall length L_1' , about 20 inch, a proximal portion 71' with a length L_2' , about 18 inch, and a diameter d_1' about 0.060 inch, a transition portion 72' extending a length L_3' , about 1 inch, and a distal portion 73' extending over a length L_4' , about 1 inch, and having a diameter d_2' , about 0.009 inch. The member 70' can be formed by extrusion or molding by techniques well-known in the art.

10 The member 70' can be processed using the techniques discussed above with respect to Fig. 3 to form the guidewire 70. For example, the draw ratio between station 42 and station 44 is about 3:1, with the ends of polymer member 70' moving apart at about 60 cm/min. The rotation rate at station 42 is about 170 rpm. The member is heated to about 250° F. After the distal portion 73' has been treated, the translation, rotation, and heating are interrupted so that compression fittings 63, 65 can be positioned along the arm 43 and clamped to the flexible distal section to reduce stress while the remainder of the member is processed. Rotation, translation, and heating are then resumed to process the rest of the member to form wire 70.

Example 2

25 Referring to Fig. 5, in an embodiment, a high torque fidelity, variable stiffness guidewire 80 is formed entirely of polymers and includes three different polymers. The guidewire 80 includes a proximal portion having a length L_1 , about 5 feet and a diameter d_1 , about 0.035 inch, a transition portion 82, of length L_3 , about 3 inch, and a distal portion 83 having a length L_4 , about 1 inch. The guidewire is formed with an inner core 84 of relatively stiff PET (intrinsic viscosity 0.75, available as Clear Tuf 8006 from Shell Corp.) extending the full length of the guidewire and having a diameter d_3 , about

0.030 inch, in the proximal portion, a taper in the transition portion, and a diameter d_2 , about 0.005 inch, in the distal portion. The guidewire also includes an outer jacket 85 of a relatively fibrillation resistant nylon (nylon-12, L-1700 or L-2101, natural (clear), available from Huls America, Inc.) that has a thickness of about 0.0025 inch in the proximal portion and extends from the proximal portion through the transition region. The guidewire further includes a soft outer layer of PEBAX (PEBAX 3533, clear, available from Atochem, France) in the transition and distal portions. The polymer element has been helically oriented as indicated by line segment 87.

Referring to Fig. 5a, the guidewire 80 can be formed from a polymer member 80' having an overall length L_1' , about 2.5 feet, and an outer diameter of d_1' , about 0.065 inch. The member 80' has a proximal portion 81' having a length of about L_2' about 2.1 inch, a transition portion of length L_3' , about 1 inch, and a distal portion 83' having a length L_4' , about 2 inch. The member 80' includes a stiff core 84' of PET with a diameter d_3' , about 0.052 inch in the proximal portions and a diameter d_2' , about 0.009 inch in the distal portions. The member 80 also includes nylon outer jacket 85 and PEBAX jacket 86. Member 80' can be coextruded according to methods described in Wang, U.S.S.N. 08/230,333 and 08/230,310, incorporated infra.

The member 80' can be processed to form guidewire 80 using the techniques discussed above with respect to Fig. 3. The draw ratio between station 42 and station 44 is about 3:1 with the stations moving apart at about 50 cm/min. The rotation rate at station 42 is about 150 rpm. The member is heated to about 200°F during processing. After the distal portions, including the PEBAX, have been processed, the translation, rotation,

- 22 -

and heating are interrupted so that compression fitting 63, 65 can be positioned along the arm 44 to hold the distal 10cm of the member and reduce stress in this flexible, soft section while the remainder of the member is processed. Rotation, translation, and heating is then resumed to treat the rest of the member. After this treatment, the member is heat set without rotation at about 300°F. It is believed in this final heating step, PET and nylon are heat set in the helically oriented configuration, while the PEBAX relaxes somewhat from the helical orientation. Alternatively, the distal end, including the PEBAX, is heat set at a lower temperature, e.g., 220° F to avoid any heat-induced retention.

Example 3

Referring to Fig. 6, a high torque fidelity, variable stiffness guidewire 90 includes a variable stiffness polymer jacket 96 and a metal core 94. The wire 90 has an overall length L_1 , about 60 inch, and includes a proximal portion 91 having a length L_2 , about 52 inch, and a diameter d_1 , about 0.018 inch, a transition section 92 having a length L_3 , about 6 inch, and a distal portion 93 having a length L_4 , about 2 inch. The inner core 94 is nitinol and has a diameter d_2 , about 0.014 inch, in proximal portions, a taper 95 in the transition region and a diameter d_3 , about 0.002 inch, in distal portions. The outer jacket 96 has variable stiffness. In the proximal portion, the jacket includes relatively stiff PEBAX (PEBAX 7033, available from Atochem), extending L_5 , about 51 inch and in the distal portion the jacket includes soft PEBAX (PEBAX 3533, available from Atochem), extending L_6 , about 9 inch. The polymer element has been helically oriented as indicated by segment line 97.

Referring to Figs. 7 and 7a, the guidewire 90 is formed from a polymer member 90' and a nitinol core 100.

- 23 -

The nitinol core has an overall length that is the same as the guidewire core, that is, L_1 , about 60 inch, a proximal portion 101 having an outer diameter d_1 , about 0.014 inch, and a length L_2 , about 51 inch, a transition portion 102 having a length L_3 , about 6 inch, and a distal portion having a length L_4 , about 3 inch, and a diameter d_3 , about 0.002 inch. The core 94 is positioned within the polymer member 90'. Polymer member 90' has an overall length L_7 , about 20 inch, and a diameter d_1' , about 0.032 inch. The member 90' includes a proximal portion 91' having a length L_8 , about 17 inch, and an inner lumen diameter d_2' , about 0.024 inch, a transition portion L_3' , about 2 inch, and a distal portion 93' having a length L_4' , about 1 inch, and an inner diameter d_3' , about 0.0035 inch. The stiffer PEBAX extends proximally about 17 inch from the proximal end. The softer PEBAX extends to the distal end of the member. The member 90' can be coextruded by techniques described in U.S.S.N. 08/230,333 and 08/230,310, incorporated infra. The variation in inner lumen diameter and outer diameter along the length can be effected by controlling air pressure and line speed of the tubing puller. Lower air pressures produce smaller inner diameters. Slower speeds produce thicker walls.

The wire 90 can be formed from the member 90' and nitinol core 94 by techniques discussed above with respect to Fig. 3. The distal portion 93' of the member 90' is positioned at station 44 and clamped such that the member and the core are held together. The proximal portion 91' of member 90' is clamped a station 42 to hold the member 90' so that it can be rotated and translated. However, the proximal portions 101 of the core extend through the member and through the station chuck so that the member 90' and core are not clamped together.

- 24 -

Referring to Fig. 7a, during processing, the member 90' is placed under tension and rotated relative to the core while heating. The polymer member 90' shrinks over the core 94 to form a unitary composite guidewire 90. The draw-ratio between station 42 and station 44 is about 3:1, with the ends moving apart at about 60 cm/min. The rotation rate is about 200 rpm. The member is heated to about 200° F.

In use, the hard plastic of the proximal end of the wire improves resistance to cutting by the beveled end of entry needles and offers good abrasion resistance. The jacket can be made thin at the proximal end which allows a larger diameter core for the same diameter wire. The stiff jacket also increases stiffness of the wire at the proximal end. The soft PEBAX of the distal end enhances flexibility and atraumatic advance. In other embodiments, with a thermoplastic polymer or a plastically degradable metal in the core at the distal end, the guidewire may be tip-formed by heating and bending prior to delivery into the body. In other embodiments, the core is a nonmetal filament, such as glass or Kevlar.

Example 4

Referring to Fig. 8, in another embodiment, a guidewire 110 is formed of an inner polymer core 111 that has been helically oriented in one direction, as indicated by segment line 113, and an outer polymer jacket 112 that has been helically oriented in the opposite direction, as indicated by segment line 115. The guidewire has an overall length L_1 , about 60 inch, and a diameter d_1 , about 0.035 inch. The core 111 has a diameter d_2 , about 0.025 inch. The jacket 112 has a thickness of about 0.005 inch. The jacket is formed of relatively stiff PEBAX (available as PEBAX 7033 from Atochem) and the core is formed of a stiff PEBAX

(available as PEBAX 6033 from Atochem). The guidewire also exhibits resistance to cutting or tear propagation in any direction, and resistance to breakage or kinking.

Referring to Figs. 9 and 9a, the guidewire 110 is formed from a core member 111' having an overall length L_1' , about 20 inch, and a diameter d_2' , about 0.045 inch. The member 111' is oriented as discussed above with respect to Fig. 3. In this example, the draw-ratio between stations 42 and 44 is about 3:1 with the stations moving apart at about 50 cm/min. The rotation rate at station 42 is about 150 rpm. The member 111' is heated to about 250° F. After this treatment the core 111 is placed within a tubular member 112' that has a length L_3 , about 20 inch, an outer diameter d_1 , about 0.060 inch, and an inner lumen diameter d_3 , about 0.040 inch.

Referring to Fig. 9b, the member 111 and 112' are processed using techniques discussed above with respect to Fig. 3 and Example 3. An end 114 of member 112' is clamped at station 44 and the other end 115 is clamped at station 42. The ends are clamped in a manner that rotates and places the member 112' under tension at end 115 without placing the member 111 under tension or torque. As member 112' is rotated under tension while heating, its inner diameter shrinks to correspond to the outer diameter of member 111. The rotation at end 115 is in a direction that is opposite the rotation used during processing of member 111'. In this manner, the inner core 111 is processed to orient the polymer in one helical direction while the member 112 has polymer orientation in the opposite helical direction.

In embodiments, the wire can be tapered or a combination of stiff and flexible polymer can be used to vary the stiffness along the length. In a particular modification of this example, rather than a guidewire,

- 26 -

the oriented member can be dimensioned for use in other torque transmission applications, such as for example, rotary ultrasound shafts, remote drilling devices (e.g., for dentistry) and arthrorectomy cutters.

5 Example 5

Referring to Fig. 10, in an embodiment, a high torque fidelity guidewire 120 includes an inner core 121 that has an axial orientation, as indicated by segment lines 123, and an outer jacket 122 that has a helical orientation, as indicated by segment line 125. The guidewire 120 has an overall length L_1 , about 60 inch, and an outer diameter d_1 , about 0.035 inch. The core 121 is formed of a relatively stiff PEBAX (available as PEBAX 7033 from Atochem) and has a diameter d_2 , about 0.030 inch. The jacket 122 is formed of a softer PEBAX (available as PEBAX 6033 from Atochem) and has a thickness of about 0.0025 inch.

The guidewire 120 can be formed by the procedure set forth above in Example 4 with the modification that
20 the core is axially oriented by placing it under tension in the apparatus described in Fig. 3 without rotation.

Other embodiments of this construction include catheters and drive shafts. Devices of this construction can exhibit very low, e.g., about 15% ultimate axial elongation.

Example 6

Referring to Fig. 11, in an embodiment, a high torque fidelity catheter 130 is formed of polymeric material. The catheter 130 has an overall length L_1 , about 42 inch, an outer diameter d_1 , about 0.078 inch, and an inner diameter d_2 , about 0.037 inch. The polymer is PEBAX (available as PEBAX 7033 from Atochem). The polymer element has been helically oriented as indicated by segment line 133.

Referring to Fig. 11a, the catheter 130 is formed from a polymer member 130' that includes an inner core 131 of high density polyethylene and an outer jacket 132 of PEBAX. The member 130' has an overall length L_1' , about 14 inch, and an outer diameter d_1' , about 0.134 inch. The core 131 has a diameter d_2' , about 0.064 inch.

The member 130' is processed by techniques described above with respect to Fig. 3. The draw ratio between stations 42 and 44 is about 3:1 with the stations moving apart at about 50 cm/min. The rotation rate at station 42 is about 150 rpm. The member is heated to a temperature of 220°F. After this treatment, the member is heated subsequently without rotation at 270°F. This subsequent heating step melts the polyethylene core 131, which relaxes the helical orientation. By relaxing the helical orientation of the polyethylene, the core can be easily stretched, reducing its diameter, and allowing it to be pulled from within the jacket.

In a modification of this example, the core 131 is formed of a noncrystalline polymer, for example polystyrene, which relaxes in the subsequent heat treatment step. In embodiments, a tube may be formed with two jacket layers that are oppositely helically oriented as described in Examples 4 and 5. The tubes can exhibit improved burst strength and resistance to kinking.

Example 7

Referring to Fig. 12, in an embodiment, a high torque, variable stiffness catheter 140 is formed of multiple polymer materials. The catheter 140 has an overall length L_1 , about 42 inch, with a proximal portion 141 having a length L_2 , about 38 inch and a diameter d_1 , about 0.078 inch, a transition portion 142 having a length L_3 , about 2 inch, and a distal portion having a length L_4 , of about 2 inch, and an outer diameter d_3 ,

- 28 -

about 0.065 inch. The catheter 140 includes a lumen extending its length having an inner diameter d_4 , about 0.037 inch. The proximal portion 141 is formed of a relatively stiff plastic, PEBAX, (available as PEBAX 7033 from Atochem) and the transition and distal portions are
5 formed of a relatively soft polymer, (available as PEBAX 5033 from Atochem). The polymer element has been helically oriented as indicated by segment line 143.

Referring to Fig. 12, the catheter 140 is formed
10 from a member 140' that has an overall length L_1' , about 14 inch. The member 140' has a proximal portion 141' with a length L_2' , about 12.6 inch, and an outer diameter d_2' , about 0.134 inch, a transition section 142' having a length L_3' , about 0.7 inch, and a distal portion 143'
15 having a length L_4' , about 0.7 inch, and an outer diameter d_3' , about 0.112 inch. The member 140' has a lumen having a diameter d_4' , about 0.064 inch. The member 140' includes a relatively stiff polymer, PEBAX, (available as PEBAX 7033 from Atochem) in the proximal
20 portion and a relatively soft polymer, (available as PEBAX 5033 from Atochem). The member 140' can be coextruded according to the methods discussed in the Wang U.S.S.N. 08/230,333 and 08/230,310 incorporated infra.

The member 140' is processed according to the
25 technique discussed above with respect to Fig. 3. The draw-ratio between stations 42 and 44 is about 3:1, with the stations moving apart at about 50 cm/min. The rotation rate is about 150 rpm. The member is heated to about 200° F.

30

Example 8

Referring to Fig. 13, in an embodiment, a high-torque fidelity guidewire 150 includes a proximal portion 152 and a distal portion 154. The proximal portion 152

includes a metal core 156, for example, stainless steel or nitinol, surrounded by a polymer jacket 158, for example, PTFE. The jacket 158 may or may not be helically oriented. The core preferably provides
5 mechanical characteristics sufficient to transmit torque with high fidelity along the length of the proximal portion 152. The metal core 156 extends a short distance into the distal portion 154 of the wire. The distal portion 154 is made of a helically oriented polymer body
10 160 that includes a first polymer portion 161, e.g., PEBAX 7033, coextruded with a second, more flexible, polymer portion 103, e.g., PEBAX 3533, which extends to a distal tip 162.

The guidewire 150 has an overall length L1, of
15 about 150 cm. The distal portion 154 has a length L2, of about 40-60 cm. The core wire 156 extends a length L3, about 3-5 cm into the distal portion 154. The outer diameter of the guidewire 150 is about 0.030 inch. The core 156 has a diameter of about 0.023 inch for most of
20 its length and tapers distally in the distal region over a length of about 6 inch to about 0.004 inch diameter. The taper begins at a point just proximal of the distal portion 160.

The guidewire 150 can be formed by procedures set
25 forth above. In a particular example, the core 156 is coated with polymer to form the jacket 158 over most of its length, while leaving a distal length of the core exposed. The distal portion 154 is formed by placing a tube-form polymer member under tension while applying
30 rotational motion to helically orient the polymer as described, e.g., with respect to Example 7 above. The tube-form member has a length of about one-third and a diameter of about two times, the dimensions of the final oriented body. The first polymer is about two-thirds the
35 length and the second polymer about one-third the length

- 30 -

of the member. The member is extruded with an inner lumen having a diameter of about 0.002-0.008" at the distal end and about 0.025" at the proximal end. The member can be oriented with a draw rate of about 3:1,
5 speed of about 50 cm/min, rotation rate of about 150 rpm and temperature of about 200°F. A tapered mandrel having a diameter corresponding to the diameter of the end of the core 156 may be provided in the end of the tube-form such that the inner lumen of the distal portion will have
10 a diameter substantially corresponding to the core after orientation. The lumen 164 in the distal portion can be open, as illustrated. Alternatively, the lumen can be closed near the distal tip 162, for example, during orientation or by heating and melting the distal tip
15 after orientation. The oriented body may also be drawn to form a tapered profile. The wire 150 is assembled by inserting the core 156 extending from the end of the proximal portion 152 into the lumen 164 and gluing the portions together using an adhesive, e.g., a
20 cyanoacrylate or U.V. curable. Any mismatch in the outer diameter of the proximal and distal portions can be smoothed by a thin layer of polymer. The wire 150 can be provided in a package in which the proximal portion 152 is coiled to a convenient size, e.g., 9-12 inch, while
25 the distal portion 154 is maintained in a generally straight configuration to assure that the portion 154 does not take a set.

Referring to Fig. 13a, a particular application of the wire 150 is to assist in delivery and operation of a
30 sphinctertome 170. The sphinctertome 170 includes a catheter body 172 with a lumen 174 and a cutting wire 176. The cutting wire 176 extends through the lumen 174 for most of its length, but near the distal end of the catheter, extends through an opening 179 in the catheter
35 wall and is fixed at a point 178 near the distal end of

- 31 -

the catheter. In a tensioned condition, the wire bows the distal portion of the catheter 172 in a manner that the wire is exposed and can be used for resection. The wire 176 is connected at its proximal end extending
5 outside the body to an RF generator (not shown).

The sphinctertome 170 can be delivered over guidewire 150 to a desired treatment site. The distal portion 154 of the guidewire has a length that is selected such that the portions of the wire that are in
10 the region of the exposed cutting wire 176 are all plastic. Typically, the wire is located in the sphinctertome such that the distal end extends about 3 inch proximally of the opening 179. When the RF energy is applied to the wire 176, the wire is not heated. The
15 distal portion 154 being made substantially of polymer, thus permits the cutting operation to be conducted while the wire extends from the distal end of the sphinctertome which can facilitate resection by guiding or stabilizing the sphinctertome. In addition, the high-torque
20 transmission characteristics of the wire assist in initial placement of the sphinctertome.

Other Embodiments

Polymer torque transmission elements can be constructed for use in many applications. For example,
25 tubes can be sized and constructed for use as guiding catheters, microcatheters (e.g., for neurovascular applications), angiographic catheters, balloon catheter shafts, and balloons. Catheters can be constructed for use in the nonvascular physiology, e.g., the urinary
30 tract, or G.I. tract. Rod-forms can be used as guidewires, as discussed, and in other applications where torque must be applied and transmitted along extended lengths. The torque transmission polymer devices may have particular advantages in applications where metal

- 32 -

components would interfere with the procedure. Examples include MRI procedures, and procedures in which RF current is applied. Sphinctertomes, for example, might be delivered without the requirement that the guidewire
5 be retracted prior to application of RF energy. Other devices such as ablation devices, e.g. heated balloons, may also be improved by the use of nonmetallic, torque transmission components. In certain MRI apparatus, such as those with C-shaped magnets, a physician can approach
10 the patient to perform a procedure during imaging. The all-polymer high torque transmission medical devices, e.g. catheters and guidewires, could be used without interference with the MRI to perform a procedure, such as a noninvasive procedure, such as catheterization. Other
15 applications for torque transmission members include rotatable drive shafts for acoustic imaging catheters and guidewires. In a particular example, shaft device is formed as a rod of PET polymer that is processed as discussed. Acoustic imaging catheters and guidewires are
20 discussed in U.S. 5,368,035, the entire contents of which is incorporated herein by reference. Other applications are in nonmedical fields where torque transmission is required. Examples include drive shafts for automobiles, boats, power tools, and elongated fluid conduits.

25 In manufacture, the ends of the polymer member can be translated at different speeds in different directions. One end could be translated while the other is held stationary. The heater could also be translated. The grip members can also be programmed to grip and
30 release the member at select locations along its length during orienting.

In manufacture of helically oriented materials with inner lumens, such as catheters, the lumen can be maintained during orientation using a teflon-coated metal
35 rod as a mandrel (for example, instead of a polymer

mandrel as described in Example 6 above). In this case, a polymer tube is oriented about the mandrel as described in Example 3. The mandrel is then pulled from the oriented member. Since the teflon coating on the exterior of the mandrel has a higher affinity for the oriented polymer than the metal rod, the metal rod can be removed leaving an oriented polymer member with a lumen including a thin coating of teflon on the lumen walls. The teflon coating on the interior of the lumen is advantageous since it can facilitate introduction of, e.g., a guidewire. In a particular example, the mandrel may be a copper rod with a thin plated silver coating. The teflon is coated over the silver at about 0.0004 inch thickness. The exposed exterior of the teflon coating is etched to enhance its ability to bond to the oriented polymer. Etching can be carried out with Teflon etchants (e.g., of the type used in the cookware industry; etching available from, e.g., HV Technologies, GA). The overall diameter of the mandrel may be, e.g., about 0.024 inch. The teflon-coated rod mandrel makes removal of the mandrel easier, particularly for oriented members of extended length, e.g., 50 or 100 cm or more. In addition, as described above, the technique provides a low friction coating on the interior of the lumen of the oriented member.

Still further embodiments are within the following claims.

- 34 -

What is claimed is:

1. An elongated medical instrument formed at least in part by an extended element that is subject to torque in use, said element being a structural body that
5 is composed of a polymer that is helically oriented about the instrument axis.
2. The medical instrument of claim 1 composed entirely of polymer.
3. The medical instrument of claim 1 wherein said
10 elongated instrument exhibits substantially 1:1 torque fidelity between proximal and distal ends.
4. The medical instrument of claim 2 wherein the element has a length of about 40 inch or more and a diameter of about 0.25 to 0.008 inch.
- 15 5. The medical instrument of claim 1 wherein said helical paths have a pitch length that is about 1.5 or more times the outer diameter of the element.
6. The medical instrument of claim 5 wherein said helical paths have a pitch length from about 2 to about 5
20 times the outer diameter of the element.
7. The medical instrument of claim 1 wherein said polymer is a semi-crystalline polymer.

- 35 -

8. The medical instrument of claim 1 wherein said polymer is selected from the group consisting of PET, Nylon, or PEBAX.

9. The medical instrument of claim 1 wherein said
5 polymer is oriented or heat set at a temperature substantially greater than sterilization temperature.

10. The medical instrument of claim 1 wherein said element is in the form of a solid polymer rod.

11. The medical instrument of claim 1 wherein
10 said element in the form of a tube.

12. The medical instrument of claim 1 in the form of a composite of an elongated metal member and said polymeric element.

13. The medical instrument of claim 1 wherein
15 said element is a coextrusion of polymers.

14. The medical instrument of claim 1 wherein said element is a coextrusion of different polymers.

15. The medical instrument of claim 1 wherein the instrument has differential stiffness along its axis.

- 36 -

16. The medical instrument of any one of claims 1, 14, or 15 wherein said element includes polymer molecules oriented on helical paths and polymer molecules oriented linearly, along said axis.

5 17. The medical instrument of any one of claims 1, 14, or 15 wherein said element includes polymer molecules oriented on multiple helical paths which are oriented about the axis in opposite directions.

10 18. The medical instrument of claim 17 wherein said element includes a first polymer layer with polymer molecules oriented along helical paths extending in one direction about said axis and a second polymer layer with polymer molecules oriented along helical paths extending in the opposite direction about said axis.

15 19. An elongated medical instrument formed at least in part of an extended element being a structural body composed of polymer, said element having a length between about 40 to 300 inch and an outer diameter of about 0.25 inch or less, said member being capable of
20 substantially 1:1 torque transmission between the proximal and distal ends without substantial whipping when said member is looped in a circle with a diameter about 5 inch at a point about half way along its length.

20. The elongated medical instrument of claim 19 in the form of a medical guidewire.

21. The elongated medical instrument 19 in the form of a medical catheter having a lumen therethrough.

5 22. The elongated medical instrument of any one of claims 19 to 21 wherein said instrument is stiffer in a proximal portion than a distal portion.

23. An elongated medical instrument formed at least in part of an extended element, said element being
10 a structural body that is composed of polymer and which is the product of the process comprising:
 providing an elongated polymer member,
 heating said polymer member above its glass transition temperature but below its melting temperature,
15 simultaneously twisting and tensioning member, and
 cooling said member to set the effect of said twisting and tensioning into said member.

24. The instrument of claim 23 comprising stretching said member by said tensioning.

20 25. The instrument of claim 24 comprising placing said polymer member in tension and rotating one end of

- 38 -

said polymer member while holding the other end rotationally stationary.

26. The instrument of claim 24 wherein said process includes simultaneously heating, twisting, and
5 stretching

27. The instrument of claim 23 wherein said process includes providing a member having differential stiffness along its length.

28. A method for forming an extended polymer
10 element that is subject to torque in use, said element being a structural body that is comprised of polymer, comprising:

providing an elongated polymer member,
heating said polymer member above its glass
15 transition temperature but below its melting temperature,
simultaneously twisting and tensioning said member, and

cooling said member to set the effect of said twisting and stretching into said member.

20 29. The method of claim 28 comprising stretching said member by said tensioning.

30. The method of claim 29 comprising placing said polymer member under tension and rotating one end of

said polymer member while holding the other end rotationally stationary.

31. The method of claim 29 comprising simultaneously heating, twisting, and stretching.

5 32. The method of claim 27 comprising a member having differential stiffness along its length.

33. The method of claim 27 comprising heating to improved dimensional stability.

10 34. The method of claim 27, comprising forming a tube by providing an elongated polymer member constructed of a jacket and core composed of different polymers,

heating, twisting, tensioning, and cooling said member,

15 heating to a temperature sufficient to melt or relax said core polymer without melting or relaxing said core polymer, and

removing said core polymer to form a lumen.

20 35. An apparatus for manufacturing an elongated element that is subject to torque in use and composed of polymer, comprising:

- 40 -

first and second holding stations spaced along a linear path and constructed to grip a preformed polymer member,

translating apparatus for moving said first and
5 second stations along said path to place said preformed polymer member in tension,

a torquing device for imposing torque on said preformed member, and

a heater located between said first and second
10 stations for heating a portion of said preformed member.

36. The apparatus of claim 35 wherein said torquing device is a rotatable chuck provided at said first holding station.

37. The apparatus of claim 35 wherein said
15 translating apparatus is constructed to move said stations along said linear path in the same direction.

38. The apparatus of claim 35 wherein said translating apparatus is constructed to move said second station faster than said first station to stretch said
20 member therebetween.

39. The apparatus of claim 35 wherein said second holding station includes a series of grippers to hold and

support a processed length of said member while other portions are processed.

40. The apparatus of claim 35 wherein said heater heats said member without contacting said member.

5 41. The apparatus of claim 40 wherein said heater is a heat gun.

42. The apparatus of claim 35 wherein said translating apparatus is constructed to vary the translation speed of said stations during the course of a
10 processing.

43. The apparatus of claim 35 wherein said torquing device is constructed to vary the torque during the course of processing said member.

44. The device of claim 35 wherein said
15 translating apparatus, torque device, and heater are constructed to reverse the direction of movement along said path while keeping said member in tension and without torquing, to heat said member to improve dimensional stability.

- 42 -

45. The device of claim 35 wherein said holding stations and torque device are constructed to contact said member on its exterior surface.

46. The device of claim 35 wherein said holding
5 stations and torque device are constructed to contact a preformed polymer tubular member with a core member extending therethrough, in a manner to permit torquing and tensioning said polymer member without torquing or tensioning said core member, while translating said
10 tubular member and core member along said path.

47. The device of claim 46 wherein said torquing element is a rotatable chuck positioned at said first station permitting gripping and torquing said polymer member without gripping or torquing said core and said
15 second station includes a gripping element that grips said polymer member and said core together.

48. An elongated medical instrument that is delivered into tortuous pathways deep within the body, comprising:
20 an extended element having differential stiffness along its length, composed of homogenous structural polymer that is helically oriented about the instrument axis.

49. The instrument of claim 48 wherein said element includes polymers of differing stiffness along its length.

50. The instrument of claim 48 or 49 wherein said element includes variable diameter along its length.

51. The instrument of claim 50 wherein said element is stiffer in proximal portions than distal portions.

52. The instrument of claim 48 wherein said instrument is a tube-form catheter.

53. The instrument of claim 48 wherein said instrument is a solid rod-form.

54. The instrument of claim 53 wherein said instrument is a guidewire.

55. An elongated implement that is torqued in use, comprising:

an extended element having a first portion composed of a polymer that is helically oriented about the instrument axis and a second portion composed of polymer in a different orientation.

- 44 -

56. The implement of claim 55 wherein said second portion is composed of polymer that is helically oriented in the rotational direction opposite the helical orientation of said first portion.

5 57. The implement of claim 55 wherein said second portion is composed of polymer that is linearly oriented.

58. The implement of any one of claims 55 to 57 wherein said first and second portions are separate layers.

10 59. The implement of any one of claims 55 to 57 wherein said first and second portions are disposed along the length of said device.

60. The implement of claim 55 in the form of a tube.

15 61. The implement of claim 55 in the form of a solid rod-form.

62. The implement of claim 55 in the form of a rotatable drive shaft.

63. An elongated implement that is subject to
20 torque in use, comprising:

an extended jacket element composed of polymer that is helically oriented about the implement axis and positioned over a core element.

64. The implement of claim 63 wherein said core
5 element is a metal wire.

65. The implement of claim 64 wherein said wire
is a super elastic material.

66. The implement of claim 63 wherein said core
is a glass filament.

10 67. An elongate implement that is subject to
torque in use, comprising:
a first portion made of an extended jacket element
comprised of polymer positioned over a core element, and
a second portion composed substantially of a
15 polymer.

68. The implement of claim 67 wherein said core
element extends partially into said second portion.

69. The implement of claim 68 wherein said first
portion has substantially greater length than said second
20 portion.

- 46 -

70. The implement of any one of claims 67-69 wherein said second portion is comprised substantially of a polymer that is helically oriented about the instrument axis.

5 71. A medical procedure on a body comprising:
 providing an elongated medical instrument formed
 at least in part by an extended element that is subject
 to torque in use, said element being a structural body
 that is comprised of polymer that is helically oriented
10 about the instrument axis,
 delivering said medical instrument into the body,
 and
 applying torque to said part comprised of polymer
 that is helically oriented about the instrument.

15 72. The procedure of claim 71, comprising:
 providing said medical instrument in the form of a
 guidewire and
 delivering said instrument into a body lumen by
 urging and torquing an end of said instrument.

20 73. The procedure of claim 71 wherein said
 procedure includes applying electrical or magnetic energy
 in proximity to said medical instrument.

74. The procedure of claim 73, wherein said procedure is a sphincterotomy procedure and said part comprised of polymer is comprised entirely of polymer near the distal end of said guidewire, said procedure
5 including delivering said guidewire into a body lumen, guiding a sphinctertome into said lumen over said guidewire, said sphinctertome including an electrically-energized resecting element near its distal end adapted to resect tissue, and resecting tissue with said
10 resecting element while maintaining said guidewire in axial location corresponding to said resecting element.

75. The procedure of claim 73 wherein said medical procedure is performed while simultaneously conducting magnetic resonance imaging of said body.

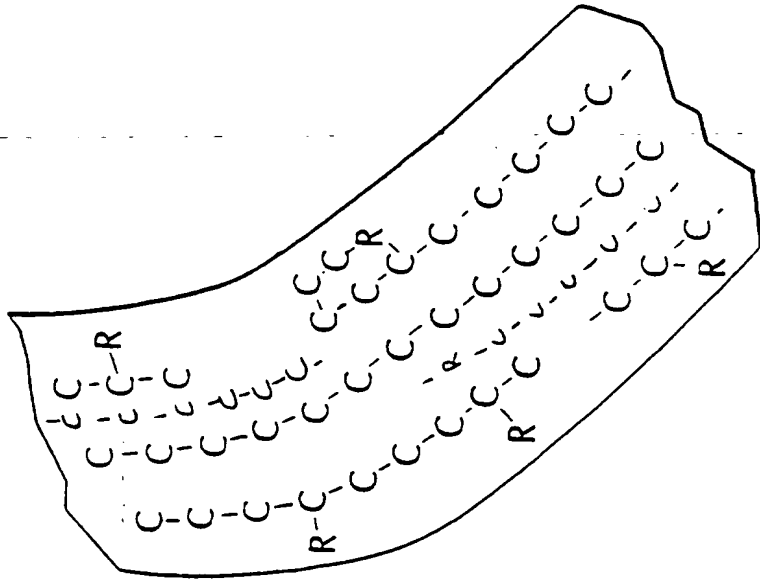
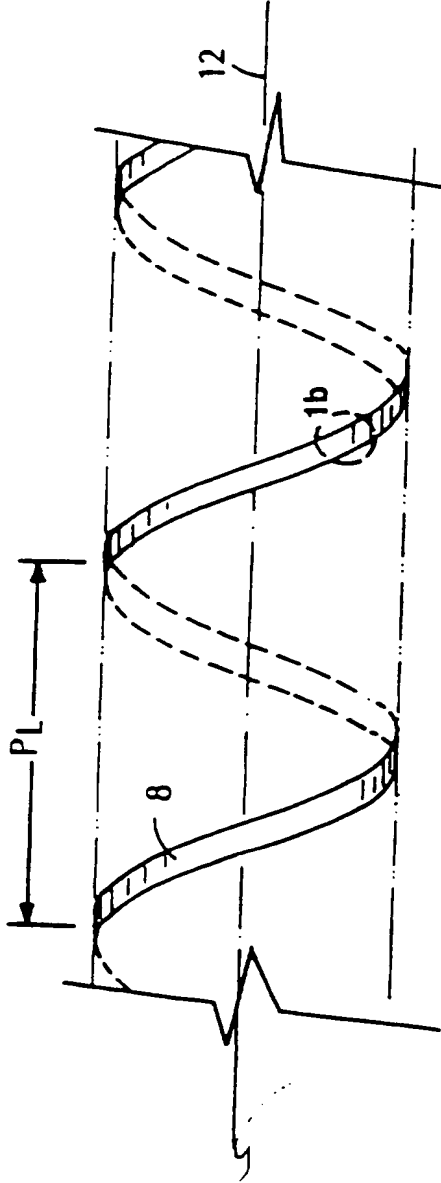
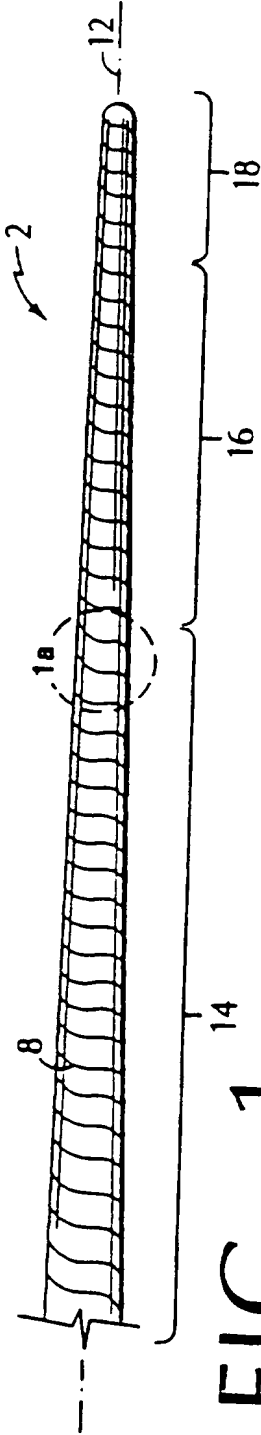
15 76. The procedure of claim 75 where said procedure is a less invasive procedure.

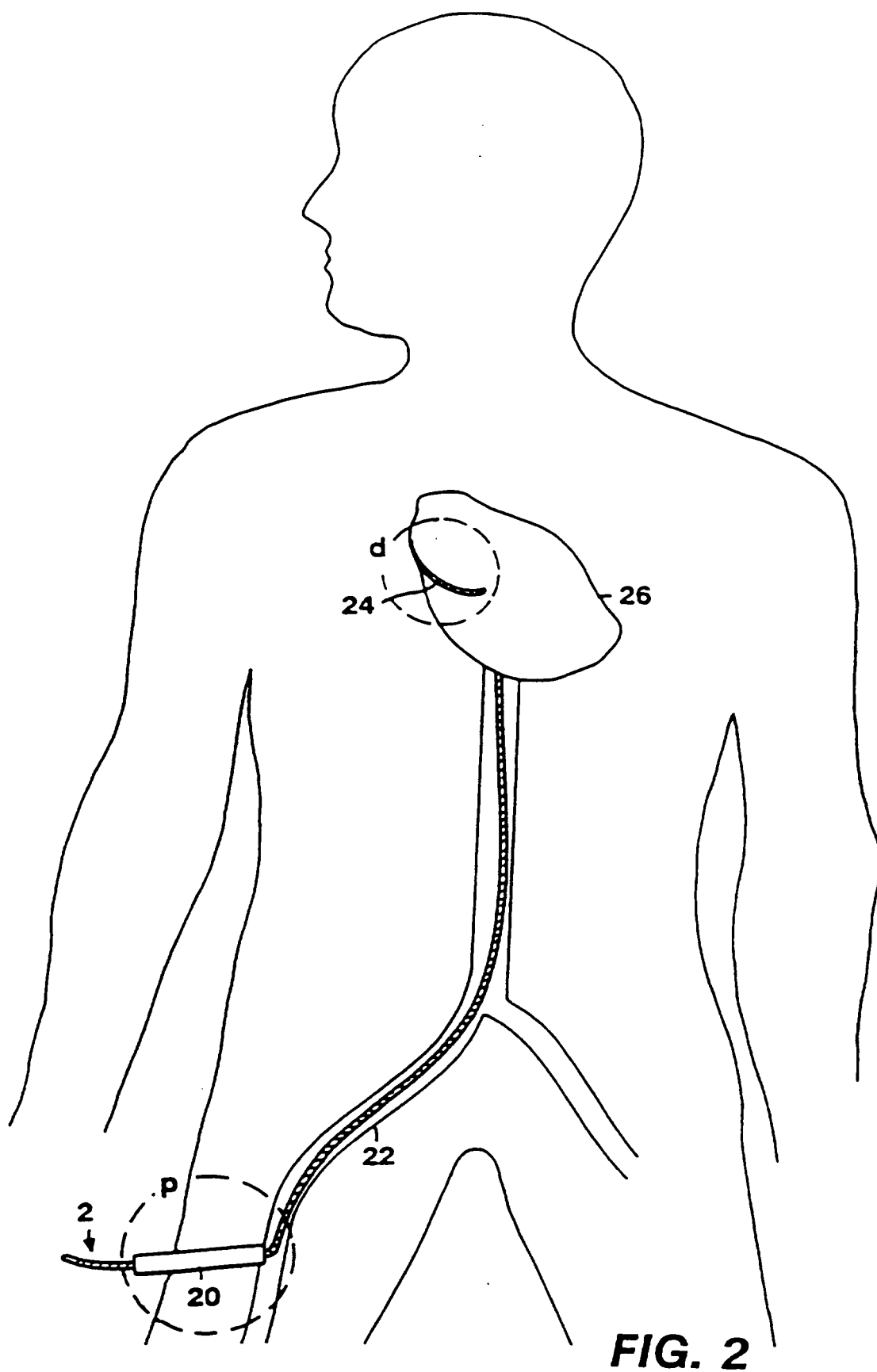
77. The procedure of claim 76 wherein said procedure includes delivering a guidewire into the body.

78. The procedure of claim 76 wherein said
20 procedure includes delivering a catheter into the body.

- 48 -

79. The procedure of claim 71 including delivering said medical instrument into the body through an entry needle formed of metal.





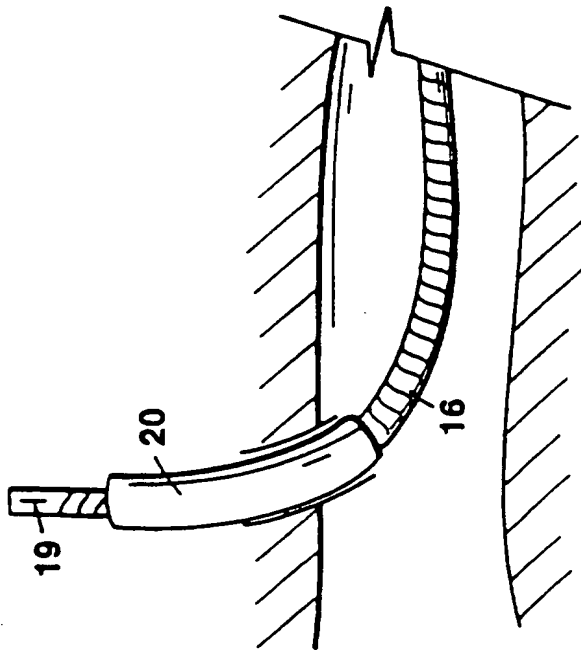
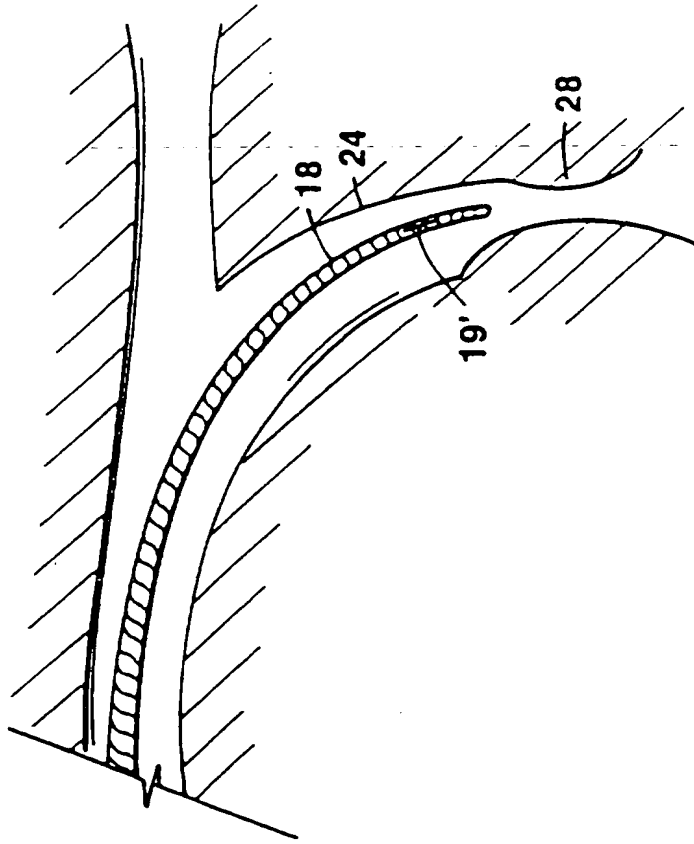


FIG. 2a



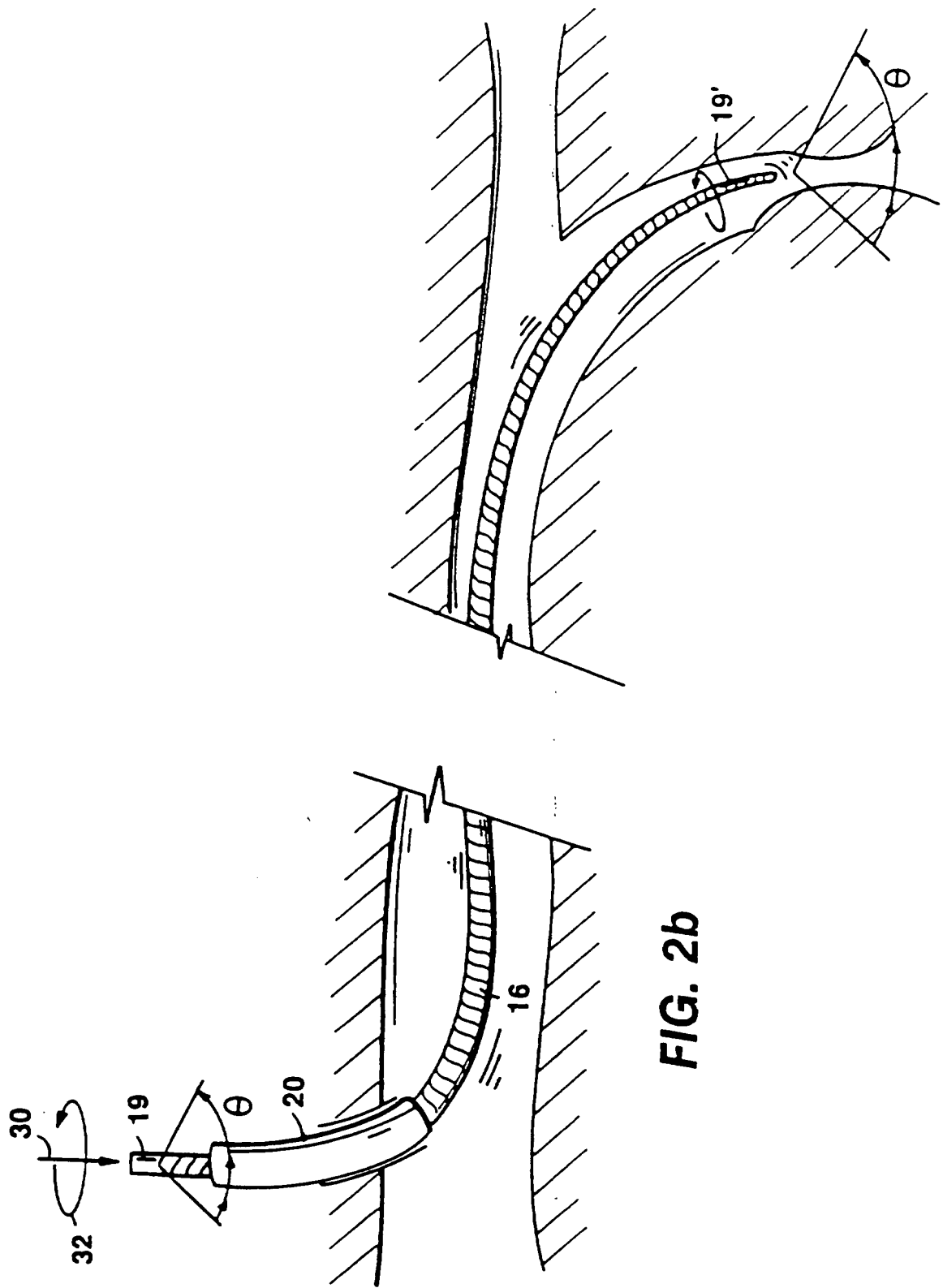


FIG. 2b

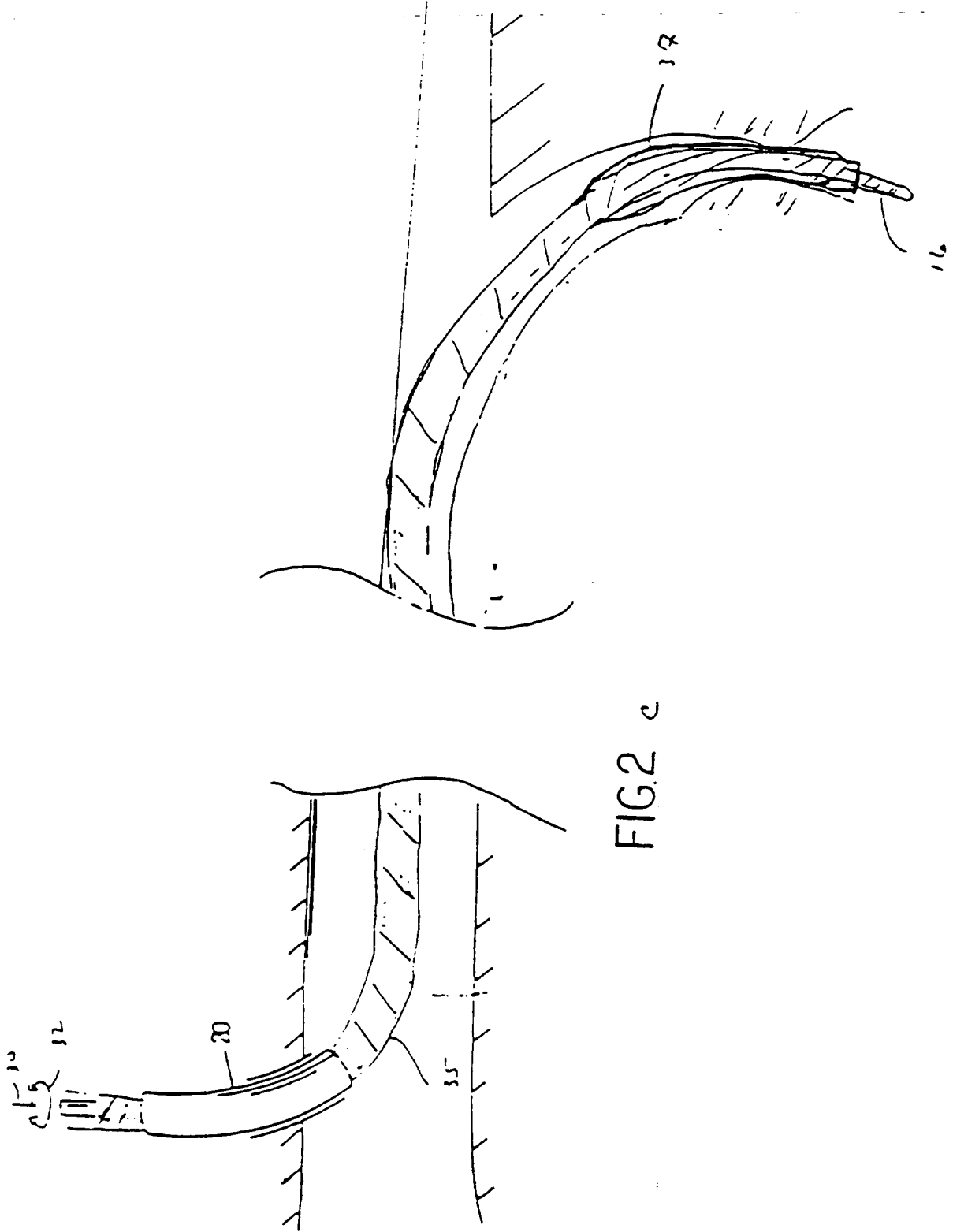


FIG. 2 c

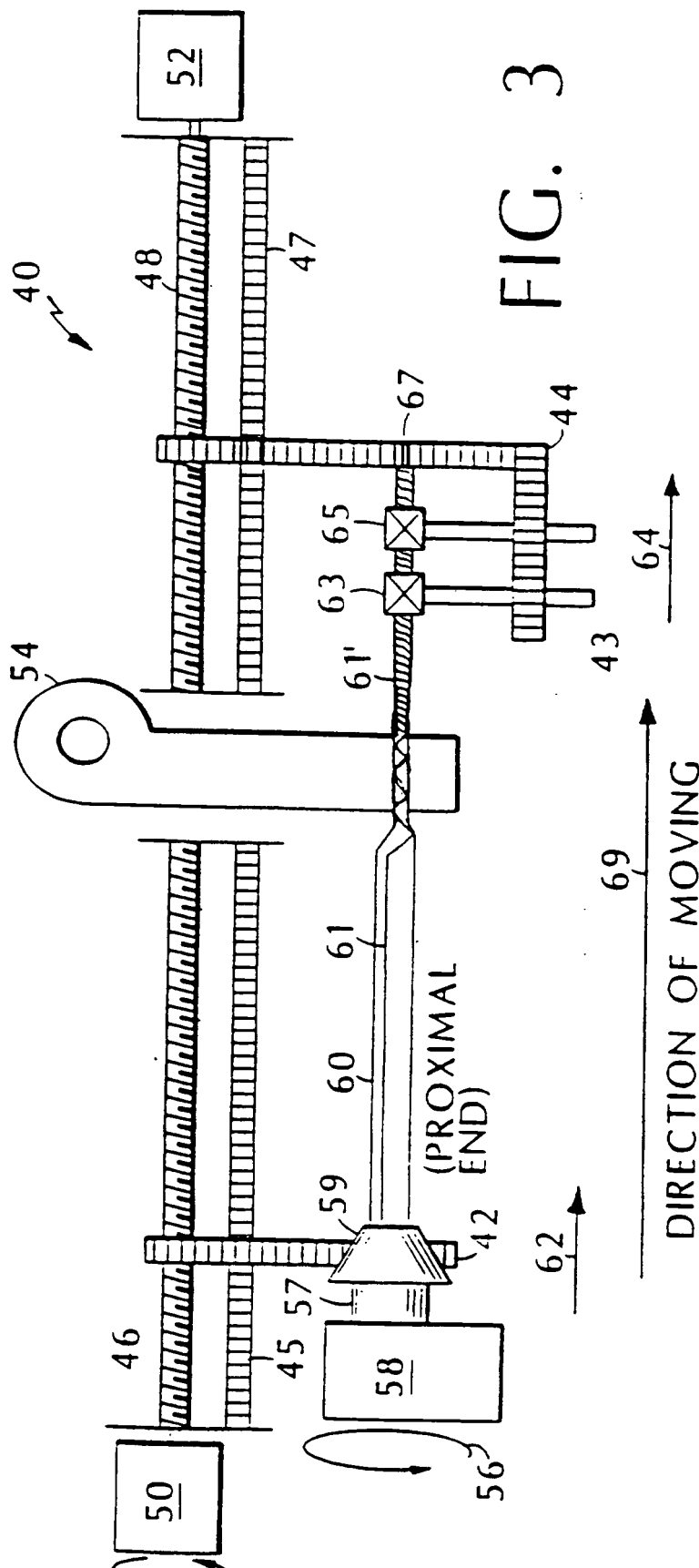


FIG. 3

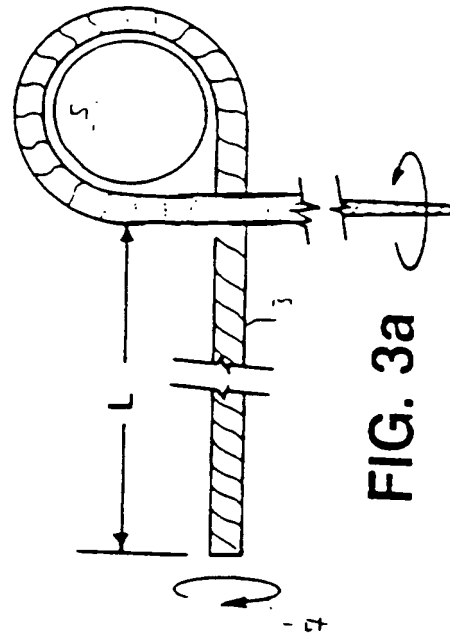
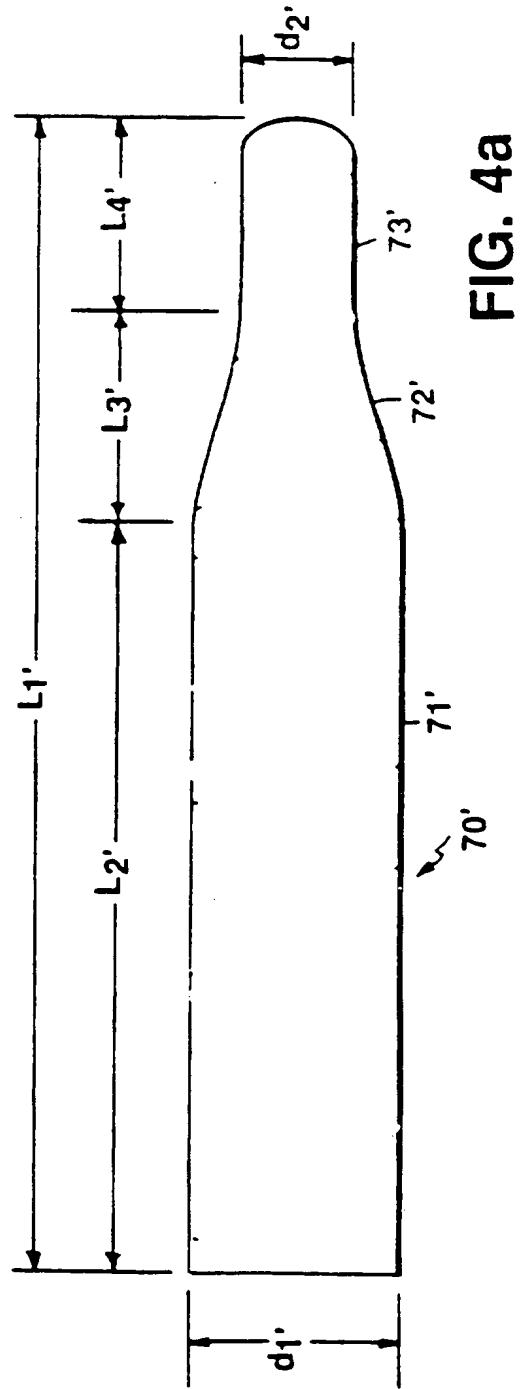
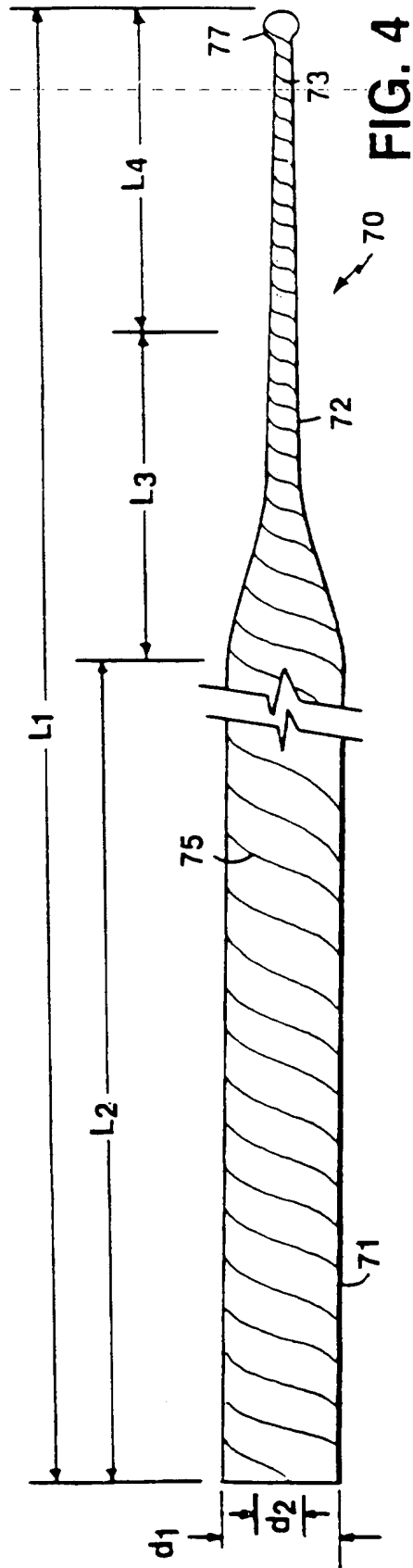


FIG. 3a



8/17

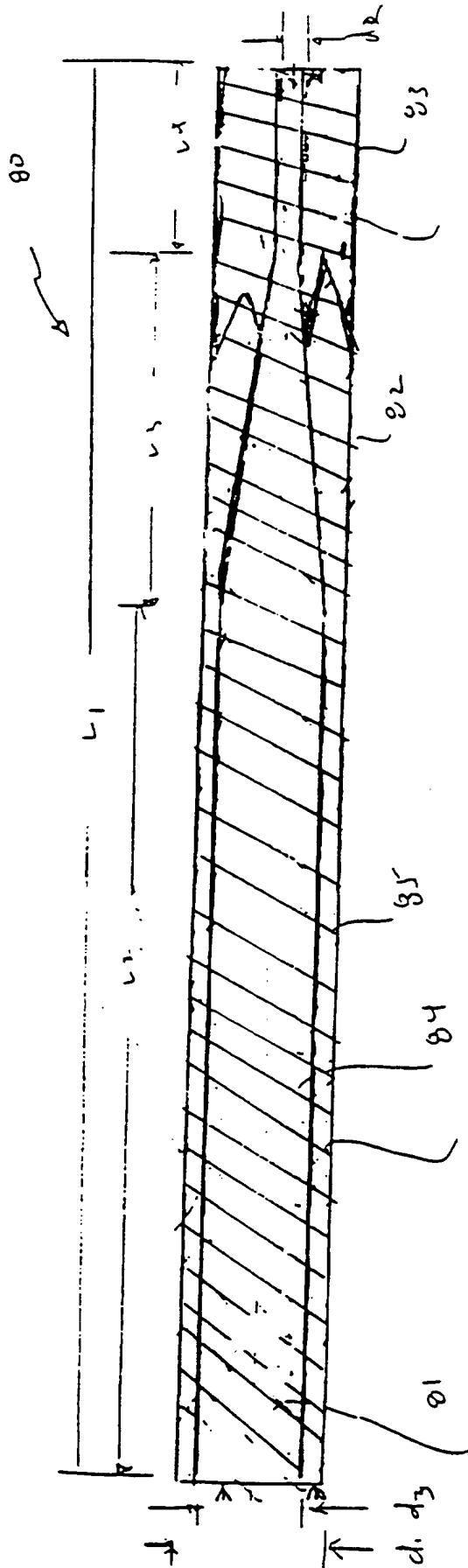


Fig. 5

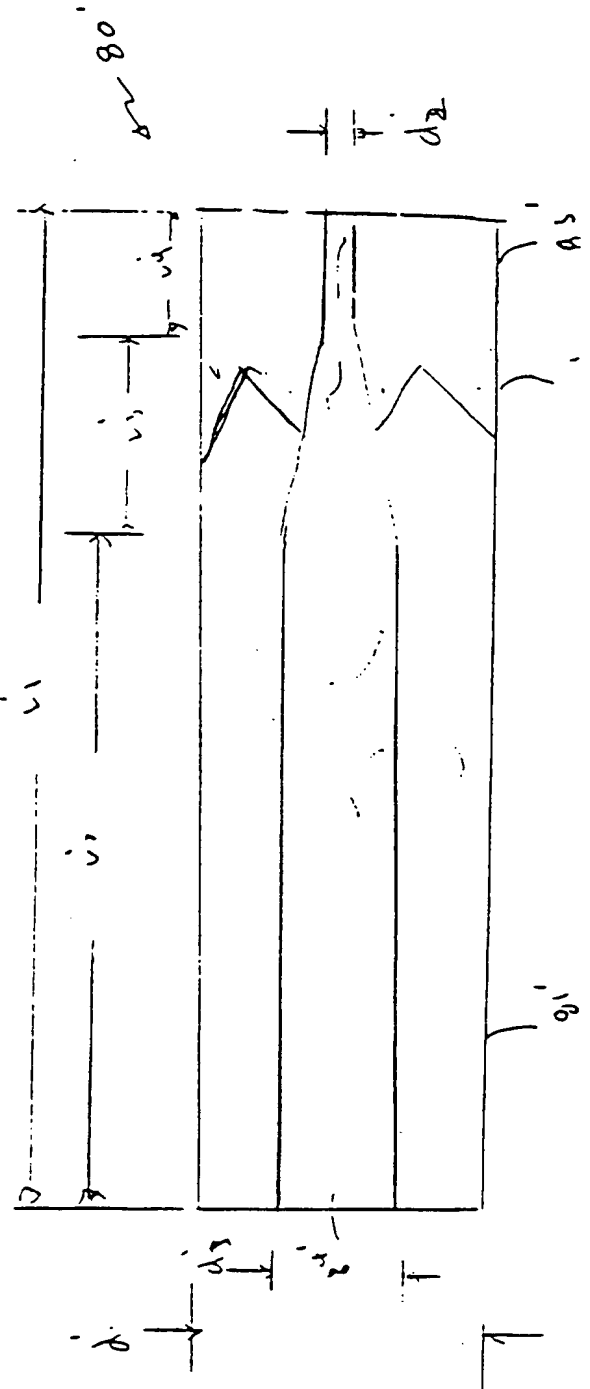


Fig. 5a

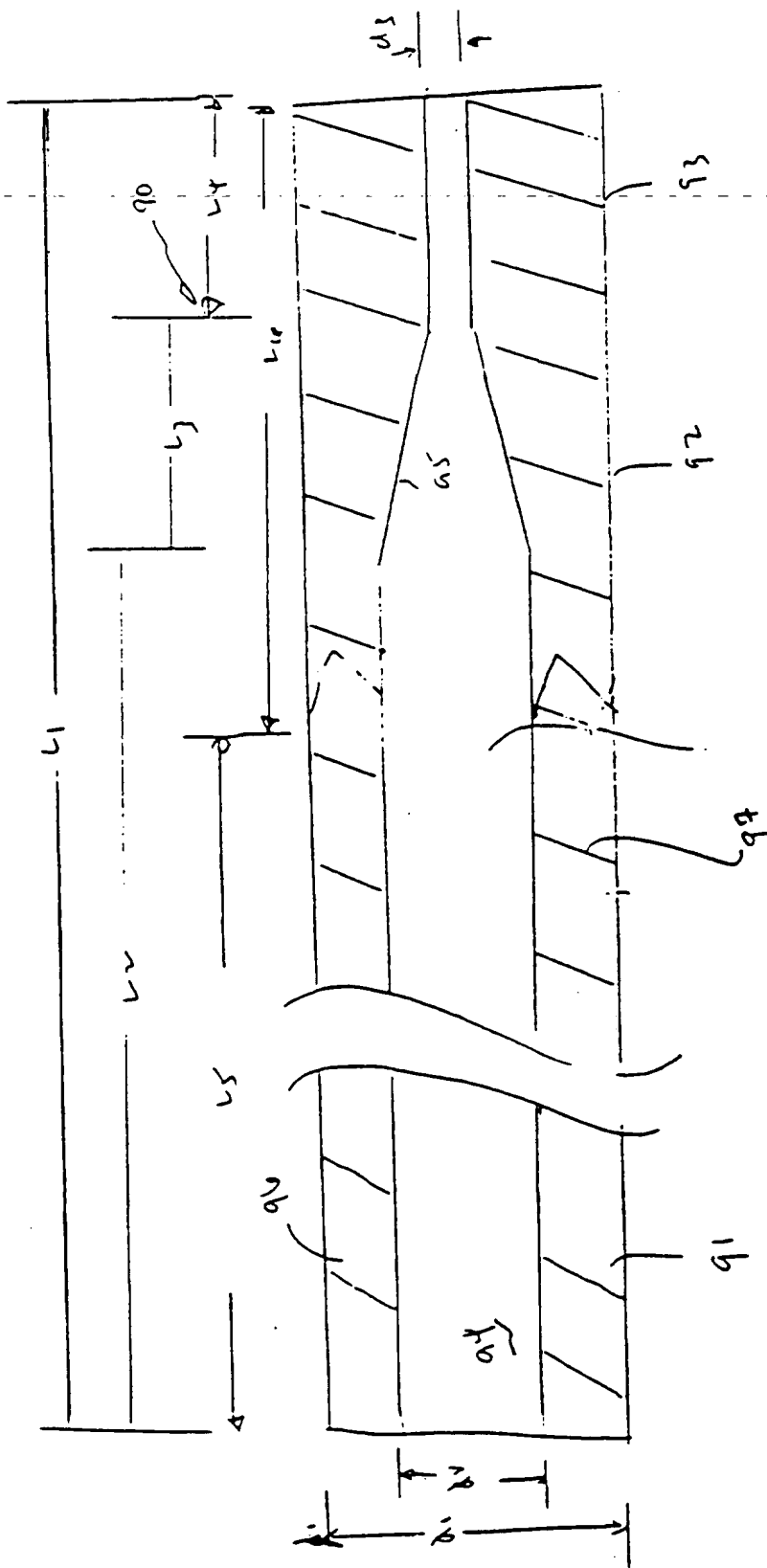
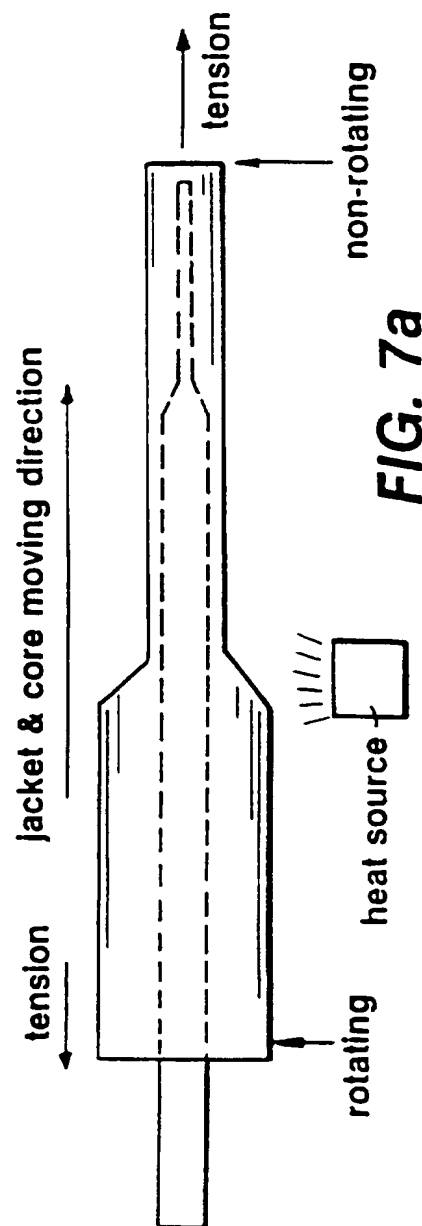
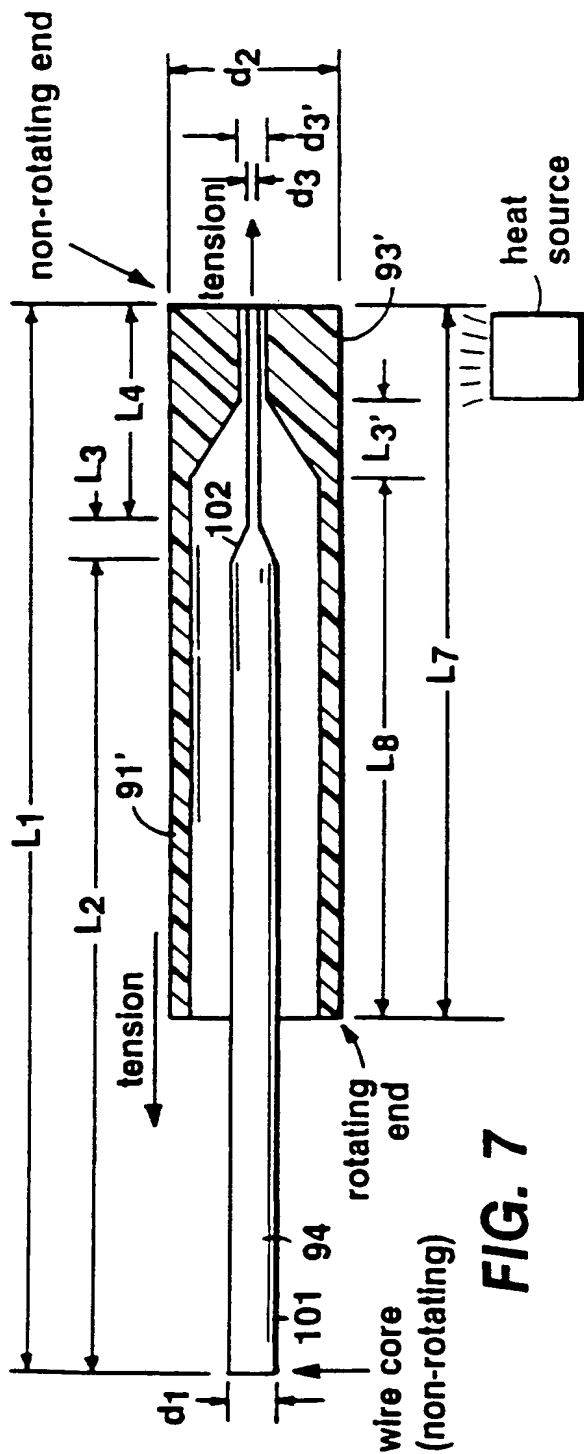


FIG. 6

10/17



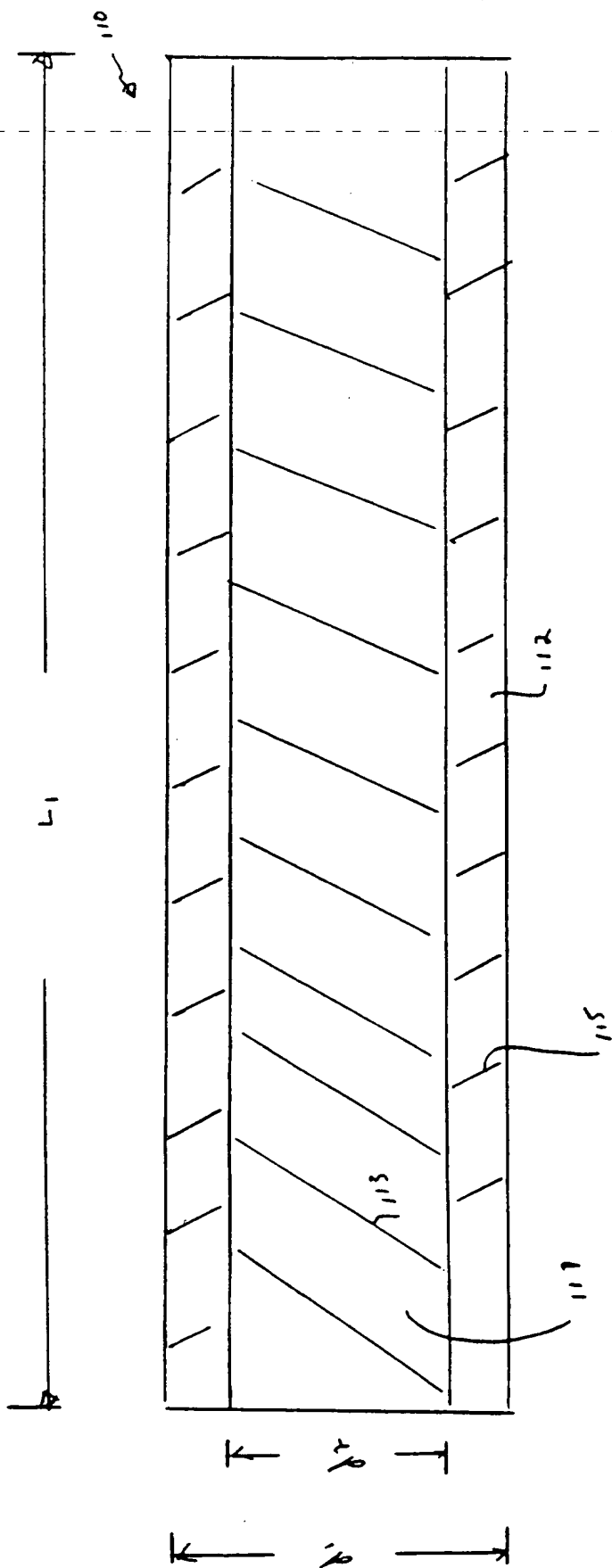
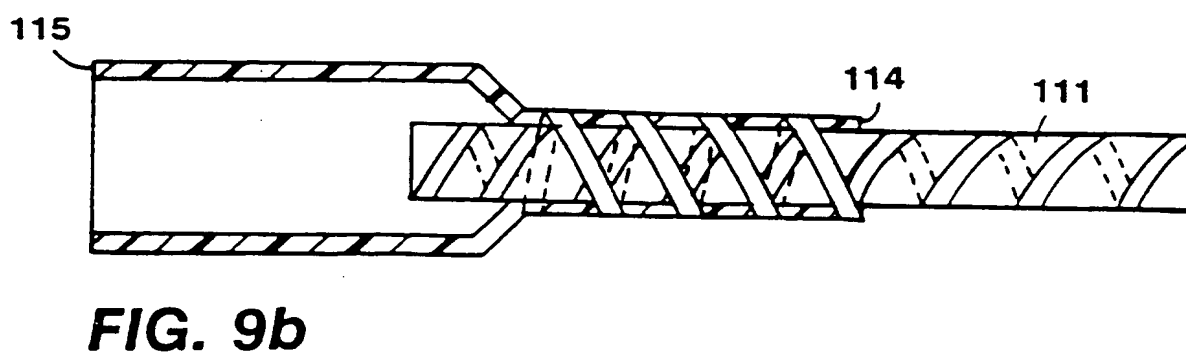
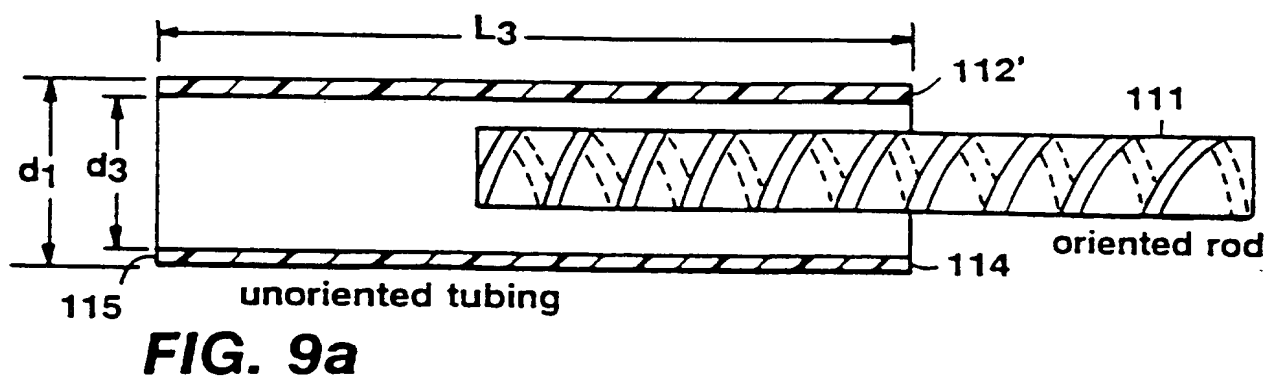
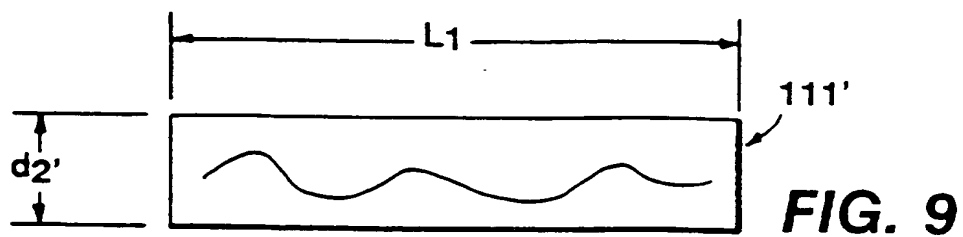
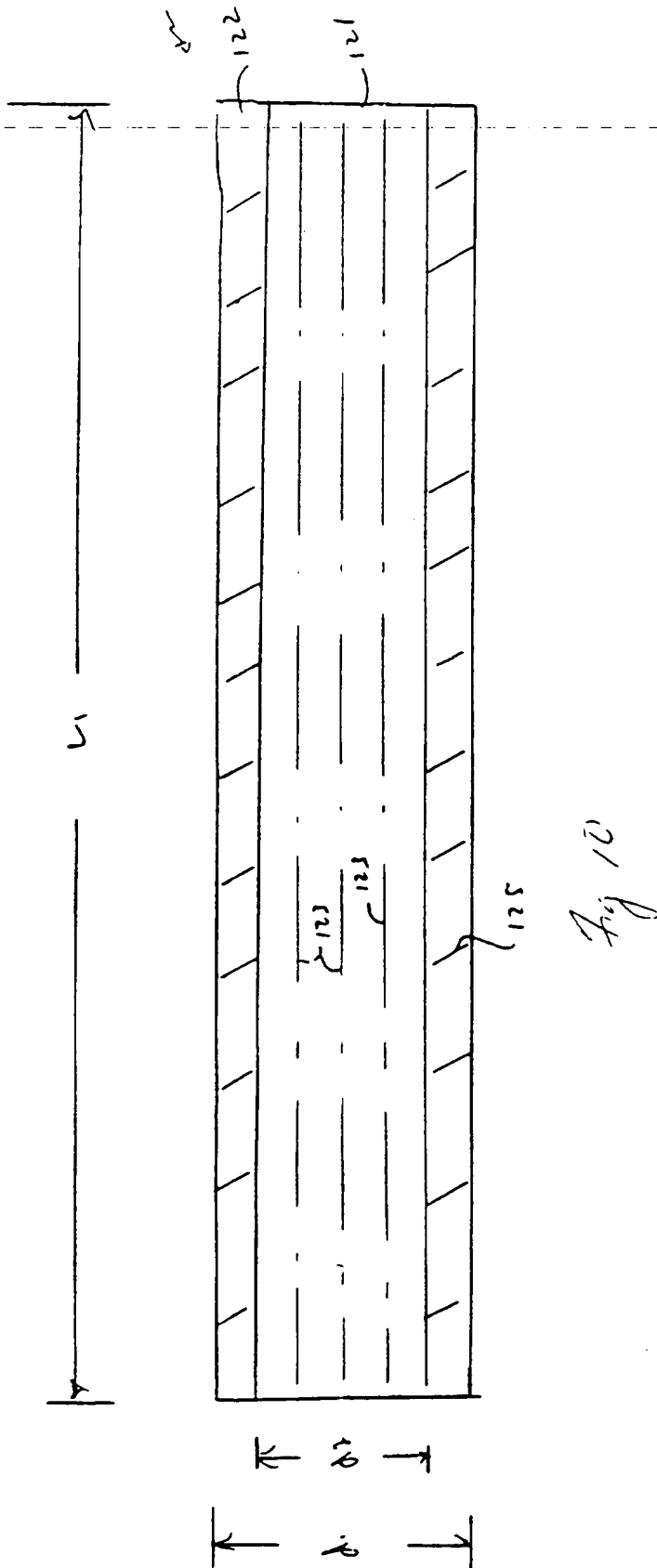
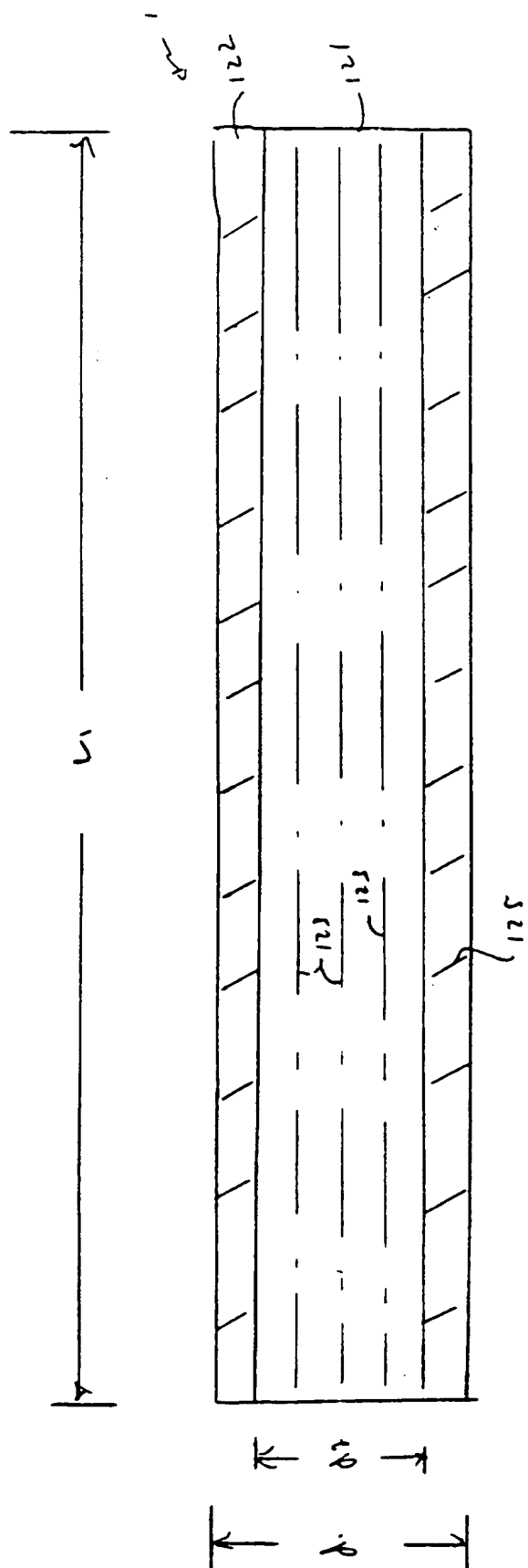


Fig. 8

12/17







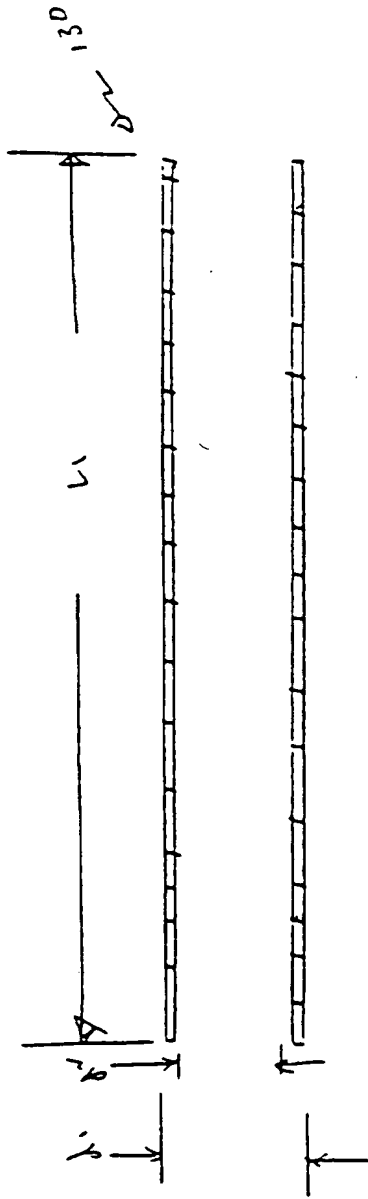


Fig. 11

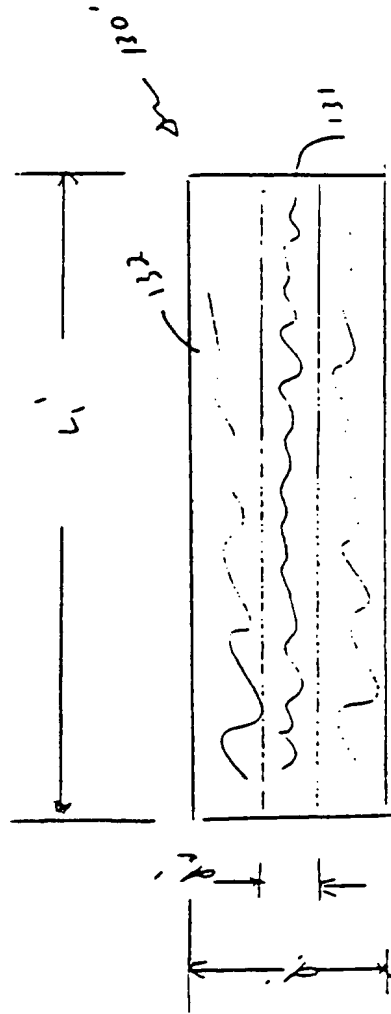
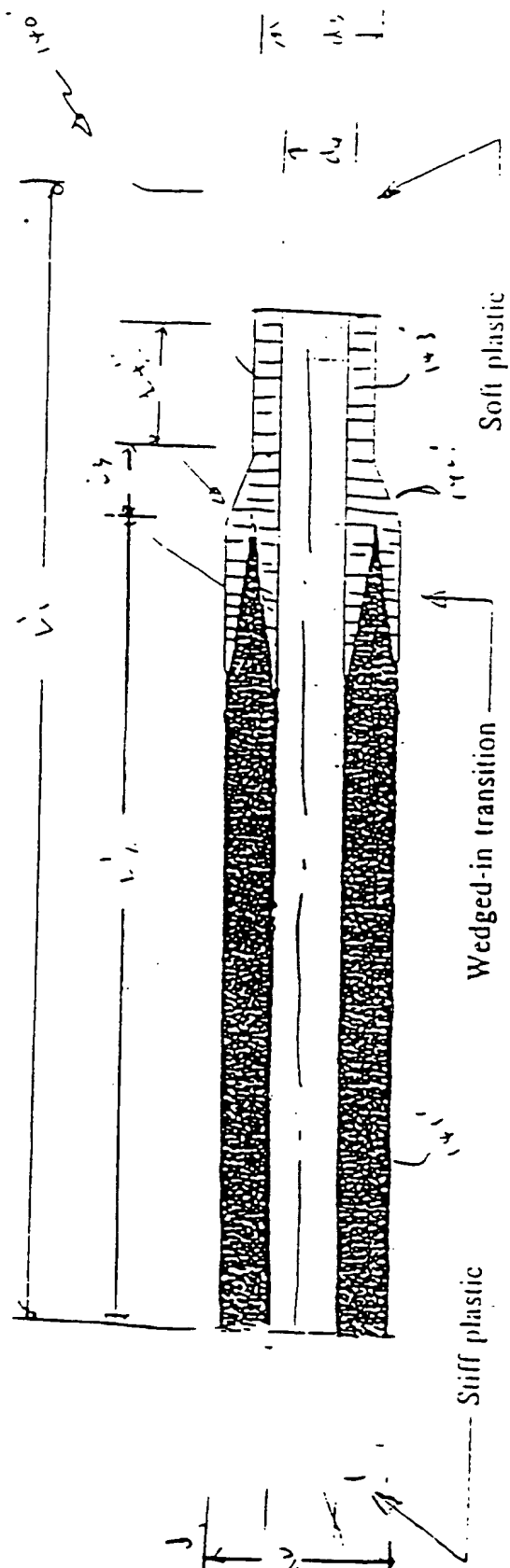
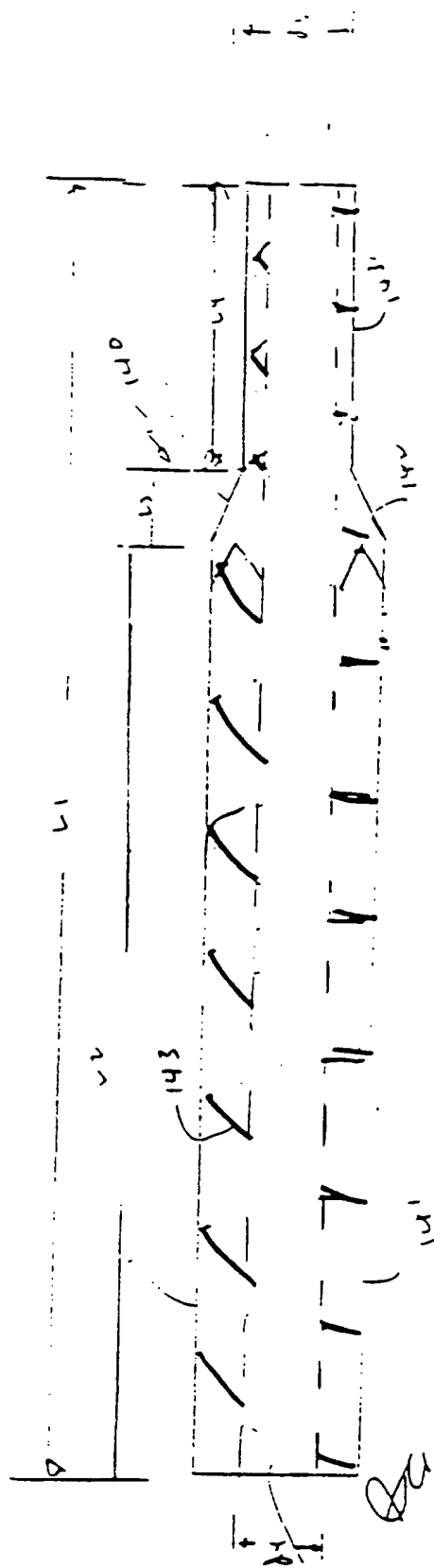


Fig. 11a



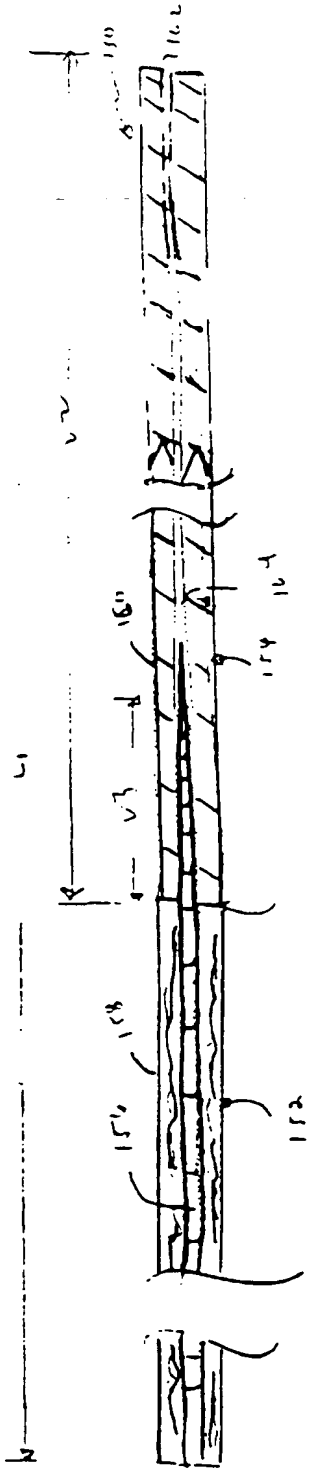


FIG. 13

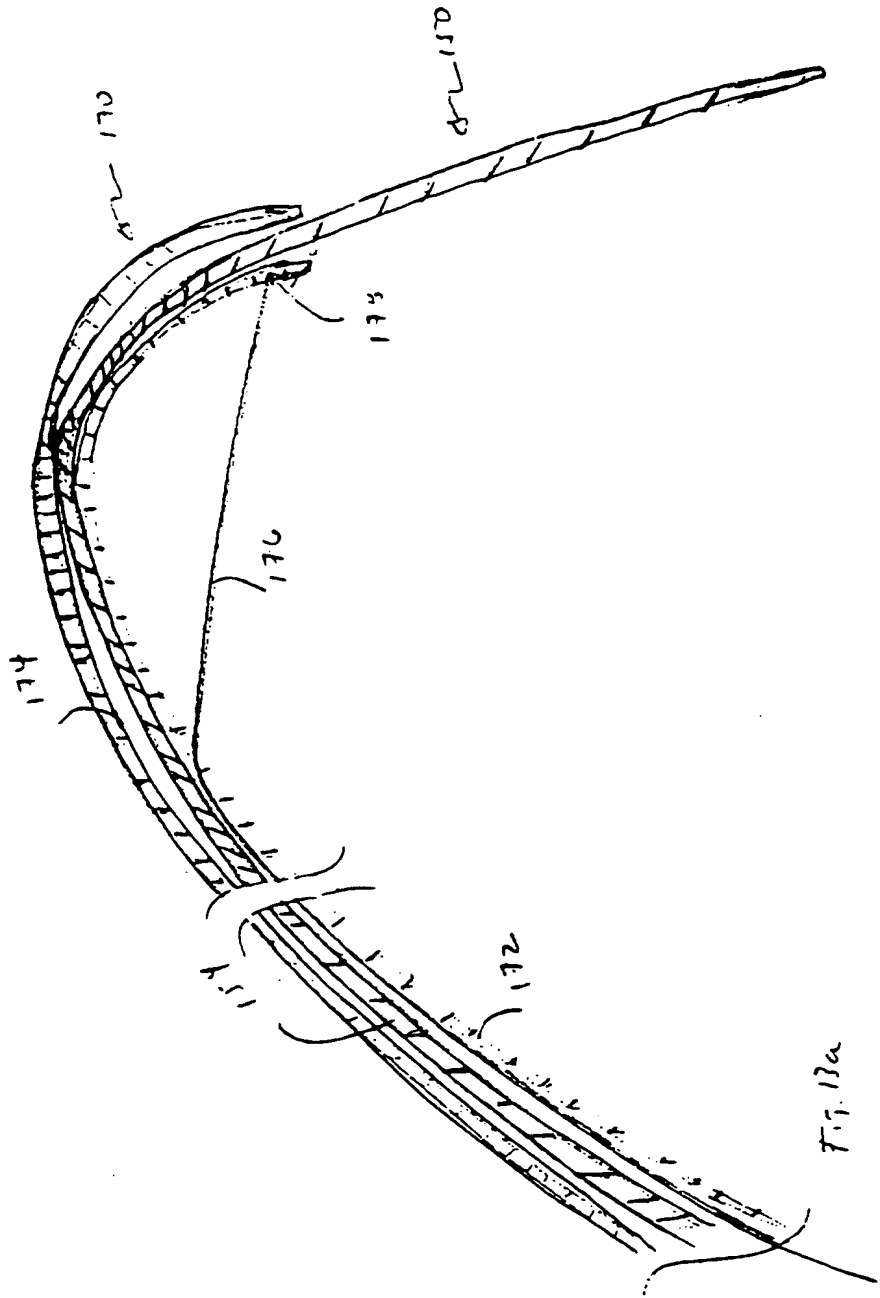


FIG. 13a

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/02265

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 5/00
US CL : 128/772

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/657, 658, 772; 604/280

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,248,305 (ZDRAHALA) 28 September 1993, see Figs. 1-3	1, 7-9, 11, 13-16, 48, 51, 52, 71 ----- 2-6, 10, 12, 17-23, 60, 53-70, 72-79
X --- Y	US, A, 5,156,785 (ZDRAHALA) 20 October 1992, see Figs. 1-3.	23-34 ----- 35-47
Y	US, A, 5,069,226 (YAMAUCHI ET AL.) 03 December 1991, see Fig. 1.	12, 46, 63-70

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

17 MAY 1996

Date of mailing of the international search report

07 JUN 1996

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer
MAX HINDENBURG

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/02265

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,932,419 (DE TOLEDO) 12 June 12, 1990, see Figs. 1 and 5.	17, 18, 55-62
Y	US, A, 5,054,501 (CHUTTANI ET AL.) 08 October 1991, see Fig. 1.	10, 20, 53, 54, 61, 72
Y	US, A, 5,024,617 (KARPIEL) 18 June 1991, see Fig. 1.	74, 74
Y	US, A, 4,874,376 (HAWKINS) 17 October 1989, see Figs. 1-3.	76-79

THIS PAGE BLANK (USPTO)



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 5/00	A1	(11) International Publication Number: WO 96/26671
		(43) International Publication Date: 6 September 1996 (06.09.96)

(21) International Application Number: PCT/US96/02265

(22) International Filing Date: 28 February 1996 (28.02.96)

(30) Priority Data:
08/395,923 28 February 1995 (28.02.95) US

(60) Parent Application or Grant

(63) Related by Continuation

US 08/395,923 (CIP)
Filed on 28 February 1995 (28.02.95)

(71) Applicant (for all designated States except US): BOSTON SCIENTIFIC CORPORATION [US/US]; One Boston Scientific Place, Natick, MA 01760-1537 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): WANG, James, C. [US/US]; 15 Massasoit Avenue, Norton, MA 02766 (US). CHIN, Albert [US/US]; 25 Bernard Street, Newton, MA 02161 (US). DAIGLE, James, B. [US/US]; 3745 Ridge View Court, Morgan Hill, CA 95037-6820 (US). DANIELS, Douglas, J. [US/US]; 15 Pudding Stone Lane, Mendon, MA 01756 (US). DEMELLO, Richard, M. [US/US]; 108 River Street, Acton, MA 01720 (US).

HARTNETT, John, F. [US/US]; 27 Beechwood Road, Wellesley, MA 02181 (US). REID, Robert, B. [US/US]; 16 Woodcrest, Westborough, MA 01581 (US). ROWLAND, Christopher, A. [US/US]; 171 Stearns Road, Marlborough, MA 01752 (US). WARICH, Charles [US/US]; 5 Genesee Circle, Milford, MA 01757 (US). SVATEK, Thomas, A. [US/US]; 581 Cross Street, Carlyle, MA 01741 (US).

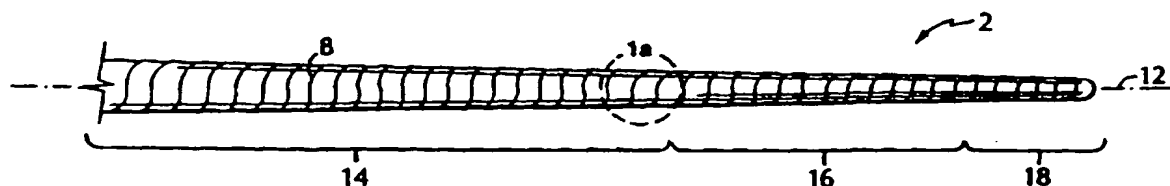
(74) Agent: GAGEL, John, J.; Fish & Richardson P.C., 225 Franklin Street, Boston, MA 02110 (US).

(81) Designated States: CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.

(54) Title: POLYMERIC IMPLEMENTS FOR TORQUE TRANSMISSION



(57) Abstract

Implements, particularly medical instruments, formed at least in part of elongated polymer members, exhibit high torque fidelity after processing with tension, heat, and twisting. The processing orients the polymer in generally helical paths so that torque imposed at the proximal end can be transmitted to the distal end without substantial whipping, even if the implement follows a long and tortuous pathway. Applications include a medical guide wire (2) with stiff portion (14), transition portion (16) and flexible portion (18), a catheter (140) and driveshaft.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France			UZ	Uzbekistan